Service Manual

Press-Mate® 8800 Series

Automatic Non-Invasive
Blood Pressure Monitor

- 8800/8800P
- 8800G/8800GP
- 8800F/8800FP
- 8800MS/8800MSP
- 8800SAT/8800SATP

COLIN
MEDICAL INSTRUMENTS CORP.
Advancing the value of life worldwide.

Caution: Federal law restricts this device to sale by or on the order of a physician.

C1730016B

The COLIN Story

From its beginning over a quarter of a century ago, COLIN MEDICAL INSTRUMENTS CORP. and its family of companies has a history of innovation and excellence, and is widely recognized for its engineering, manufacturing, and marketing of non-invasive blood pressure monitoring instruments. The expertise of research facilities around the world, including internationally renowned Southwest Research Institute in San Antonio, Texas, and Stanford Research Institute International in Menlo Park, California, has contributed to Colin's success.

Technological Leadership
COLIN'S commitment to research has generated the maximum return. COLIN is the only company in the world with three distinct non-invasive blood pressure measurement technologies: the **auscultatory** method, which uses a microphone to detect Korotkoff sounds is found in COLIN'S ambulatory and stress test blood pressure monitors; the **oscillometric** method, found in COLIN'S vital signs monitors; and **arterial tonometry**, an exceptionally unique technology offering continuous non-invasive blood pressure for monitoring and diagnostic purposes.

Over 450,000 non-invasive blood pressure instruments have been manufactured by COLIN and are marketed worldwide under COLIN trade names and those of many other respected manufacturers, such as North American Draëger, Nellcor, Fresenius, B. Braun, Ivy Biomedical and Quinton, who use COLIN's technology (OEM) inside their own brand-name products.

Consistent with worldwide research efforts on blood pressure and non-invasive monitoring, Colin has wisely invested in studies conducted in collaboration with leading U. S. research institutes and universities. These projects have resulted in a number of significant contributions to patient monitoring technology, including Colin's continuous beat-to-beat non-invasive blood pressure monitor based on arterial tonometry. Today, Colin has more than 150 employees, worldwide, who are exclusively assigned to engineering research.

Market Served
Non-invasive blood pressure instruments currently manufactured by COLIN range from monitoring devices (portable vital signs monitors and multiparameter patient monitors) to diagnostic devices (stress-test monitors and units featuring arterial tonometry). These have applications in clinical areas, including anesthesia, post anesthesia care, critical care, emergency room, labor and delivery, neonatal intensive care, medical surgical nursing, cardiology, dialysis, electro physiology, as well as other special procedure labs.

Understanding the needs of the customers it serves in numerous segments of the health care market is only one part of Colin's successful business strategy. Extensive research and development, professional sales representatives, an expert technical staff, responsive customer services, and dedicated management team all play essential roles in Colin's commitment to its customers and the advancement of health care delivery, worldwide.

The Future Plan
In a class by itself, COLIN MEDICAL INSTRUMENTS is committed to distributing the highest quality products by manufacturing devices that are equipped with unsurpassed speed, accuracy, reliability, quality and comfort.

Please visit our website at www.colinmedical.com.

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1.0 Introduction

1.1 Purpose of This Manual

This manual is intended as a guide for technically qualified personnel, and provides limited service and repair information for the COLIN Press-Mate **Model 8800 Series blood pressure, temperature, pulse rate, and SpO2 measuring and monitoring devices** and all integrated components thereof. As a prerequisite to using this document while servicing or repairing this equipment, technical personnel should have a comprehensive understanding of the unit's operation, as well as the information contained in this service manual.

1.2 How To Use This Manual

The information contained in this service manual is divided into sections, as identified in the Table of Contents. Each section and its contents are numbered and divided by tabs and labels to help the reader locate specific references. Page numbers are sequential as per each section.

1.3 General Information

Model 8800
The Press-Mate Model 8800 Monitor is a stand-alone, non-invasive electronic device that measures blood pressure and pulse rate and digitally displays the measurement values. This portable adult, pediatric and neonatal blood pressure monitor is designed to measure, non-invasively and automatically, systolic, mean and diastolic blood pressures and pulse rate. Desired values can be measured on demand, or the unit can be programmed to automatically monitor and record all data, except temperature, either continuously or at selected intervals. An alarm function is incorporated, which can be set with high and low limits. The memory storage capacity of the press-Mate is 400 lines of data, more than any other non-invasive blood pressure (NIBP) stand-alone monitor. The monitor is available with or without a built-in printer. Monitors with built-in printers can print all stored patient data on command.

Model 8800F
The Press-Mate **Model 8800F** Monitor is a portable adult, pediatric and neonatal blood pressure monitor designed to measure, non-invasively and automatically, systolic, mean and diastolic blood pressure, pulse rate and temperature via an electronic predictive thermometry. Predictive thermometry measurements are made with the Sherwood FILAC® F2000 electronic thermometer. This monitor is available with or without a built-in printer.

Model 8800MS
The Press-Mate **Model 8800MS** Monitor is a portable adult and pediatric blood pressure monitor designed to measure, non-invasively and automatically, systolic and diastolic blood pressure, pulse rate and temperature via tympanic thermometry. Tympanic thermometry measurements are made with the FirstTemp® Genius® thermometer. The Genius is integrated with the Press-Mate to allow the data transmission of the temperature values. These values are then displayed on the Temp LEDs of the Press-Mate, as well as placed in the Press-Mate's memory. The monitor is available with or without a built-in printer.

Model 8800SAT
The Press-Mate **Model 8800SAT** Monitor is a portable adult, pediatric and neonatal blood pressure monitor designed to measure, non-invasively and automatically, systolic, mean and diastolic blood pressure, pulse rate and pulse oxygen saturation. This monitor is available with or without a built-in printer.

1.4 Service Limitations

Maintenance and repair services performed by user personnel on the equipment covered in this manual applies only to products that are out of warranty and should be performed only by qualified service technicians.

1.5 Warranty

COLIN warrants the initial purchaser ("Purchaser") that each new **Press-Mate 8800 Series** monitor, including the accompanying reusable accessories (the "Warranted Products") purchased from COLIN or an authorized COLIN distributor will be free from defects in workmanship and materials for the term specified in your purchase agreement.

COLIN'S only obligation under this warranty are (1) to repair or replace any Warranted Product (or part thereof) that COLIN reasonably determines to be covered by this warranty and to be defective in workmanship or materials and (2) to provide loaner equipment in the circumstances set forth in the manual.

If, on the basis of this information provided by the Purchaser, COLIN reasonably believes that the defect is covered by this warranty, COLIN will authorize Purchaser to return the Warranted Product (or part thereof) to COLIN. COLIN shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become COLIN'S property. In the course of warranty service, COLIN may, but shall not be required to, make engineering improvements to the Warranted Product or part thereof.

1.6 Loaner Policy

Purchaser is responsible for any damage to or loss of any loaner equipment while it is at Purchaser's location. Purchaser must return loaner equipment within 10 days after receiving the repaired or replaced Product or receiving notice from COLIN that the Product returned by Purchaser is not covered by the warranty. If Purchaser does not return loaner equipment within 20 days after the return due date, then Purchaser agrees to pay COLIN the reasonable value of the loaner equipment or a reasonable daily rental fee, whichever COLIN selects.

1.7 Shipping Procedures

If COLIN reasonably determines that a repair or replacement is covered by the warranty, COLIN shall bear the costs of shipping the loaner product and the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product.
Products shipped by Purchaser under this warranty shall be suitably packaged to protect the Product. If Purchaser ships a Product to COLIN in unsuitable packaging, any physical damage present in the Product on receipt by COLIN (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the Purchaser.

1.8 Return of Unit

Prior to returning a unit:

* Call Technical Services at 800-829-NIBP (6427), explain problems observed, verify warranty, and obtain a Return of Merchandise Authorization (RMA) number.
* Remove all accessories from the unit.
* Package the unit appropriately to ensure the monitor will be undamaged during transit. If a loaner unit was required, place the unit to be returned in the same packaging material the loaner was received in.
* Ship to: COLIN MEDICAL INSTRUMENTS, CORP., 12691 Silicon Drive, San Antonio, Tx 78249-3429.

Write "Attn: RMA Number _____" on the address label.

1.9 Exclusions

This warranty does not extend to any Warranted Products or parts thereof that have been subject to misuse, neglect or accident; that have been damaged by causes external to the Warranted Products, including but not limited to failure of or faulty electrical power; that have been used in violation of COLIN'S instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; or that have been modified or improperly disassembled, serviced, or reassembled by anyone other than COLIN, unless authorized by COLIN.

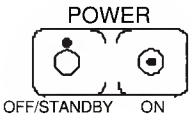
COLIN makes no warranty (a) with respect to any disposable products or any other products that are not Warranted Products, (b) with respect to any products purchased from a person other than COLIN or a COLIN-authorized distributor, or (c) with respect to any product sold under a brand name other than COLIN.

COLIN will not be responsible for the effect on safety, reliability, and performance of the Product if: (a) assembly operations, extension, readjustments, modifications, or repairs are carried out by persons other than COLIN or persons authorized by COLIN to perform repair service on COLIN'S behalf; or (b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or (c) the Product is not used in accordance with COLIN'S instructions for use.

In the event of a defect in the Product, COLIN will be liable for injury or death of any actual person, or damage to property, to the extent, but only to the extent, that such liability is mandated under laws applicable to manufacturers in general and to manufacturers of the category of products to which the Product belongs.

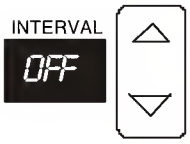
2.0 Physical Description

2.1 Front Panel Functions



Power Switch
Controls the AC or selected battery power to the monitor

Start/Stop Switch
Starts initial cuff inflation. If pushed during inflation, it automatically stops and deflates the cuff.



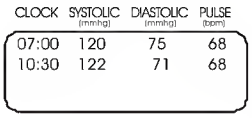
Interval Switch
Selects either "NO INTERVAL" or "CONTINUOUS" Interval for consecutive blood pressure monitoring.

Alarms - SET, HIGH, LOW, MUTE
Set - Sets LCD in alarm mode
High - Sets high alarm limit
Low - Sets low alarm limit
Mute - Silences audible alarm

List
Scrolls up or down to read previous data. Pressing the scroll down switch for more than three (3) seconds will enable "ALL DATA" print mode. Pressing both the up and down switches for three (3) seconds will erase all stored data.

Paper feed
Feeds the printer paper

Clock/Elapsed Time Display
Alternately displays 24 hour clock and elapsed time meter.



LCD Screen
Displays data for previous four (4) measurements; maximum of 400 lines of memory can be scrolled. Alarm limits and error codes are also displayed on this screen.

Adult/Neonatal
Displays which mode the monitor is in, adult/pediatric or neonatal.

Systolic Display
Displays systolic pressure.

Mean Display
Displays mean arterial pressure. Also displays the pressure of the cuff during measurement.

Diastolic Display
Displays diastolic pressure

Pulse Rate Display
Displays pulse rate (beats per minute) upon completion of measurement.

Systolic Alarm Display
Displays systolic High and Low alarm limits.

Pulse Level Indicators
Displays a red signal proportional to the amplitude of the oscillation the monitor senses during cuff deflation.

Battery Indicator
Lights in green during battery operation; flashes in red when battery is low.

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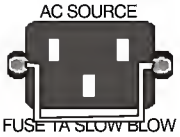
2.2 Rear Panel Functions

Grounding Terminal



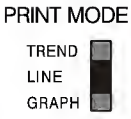
A/C Power Cord Receptacle

1 Amp Line Fuses

Measurement Mode Switch
Selects either Adult/Pediatric or Neonatal Mode

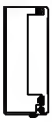
Display ON/OFF Switch
In the "OFF" position, LED display on front panel will show "---"

Print ON/OFF Switch
In the "ON" position, the printer prints after every measurement and upon alarm violations. In the "OFF" position, the unit only prints upon alarm violations.



Print Mode Switch
Selects print modes: Trend, Line List , or Graphic Oscillation.

RS 232 Data Interface
Allows the monitor to be interfaced with computer, data acquisition systems, etc.



Battery Box

2.3 Tympanic Thermometry Functions – 8800MS/MSP

Release Button
When pressed, this button discharges the temperature probe cover from the tip of the probe.

Scan Button
When pressed, this button initiates a temperature measurement.

Mode Button
This button is used to change operational modes as well as change temperature range from ^{0}C to ^{0}F.

Temperature Window
Displays temperature value.

2.4 N-20PA Pulse Oximeter Functions – 8800SAT/SATP

Printer ON button

Printer paper advance button

Date/Day

Battery check button

Measure button

SpO$_2$ Percent oxygen saturation

Pulse Search Pulse search indicator

Low Battery Low battery indicator

Oxygen Saturation Display

Pulse Rate Display

Pulse Amplitude Indicator

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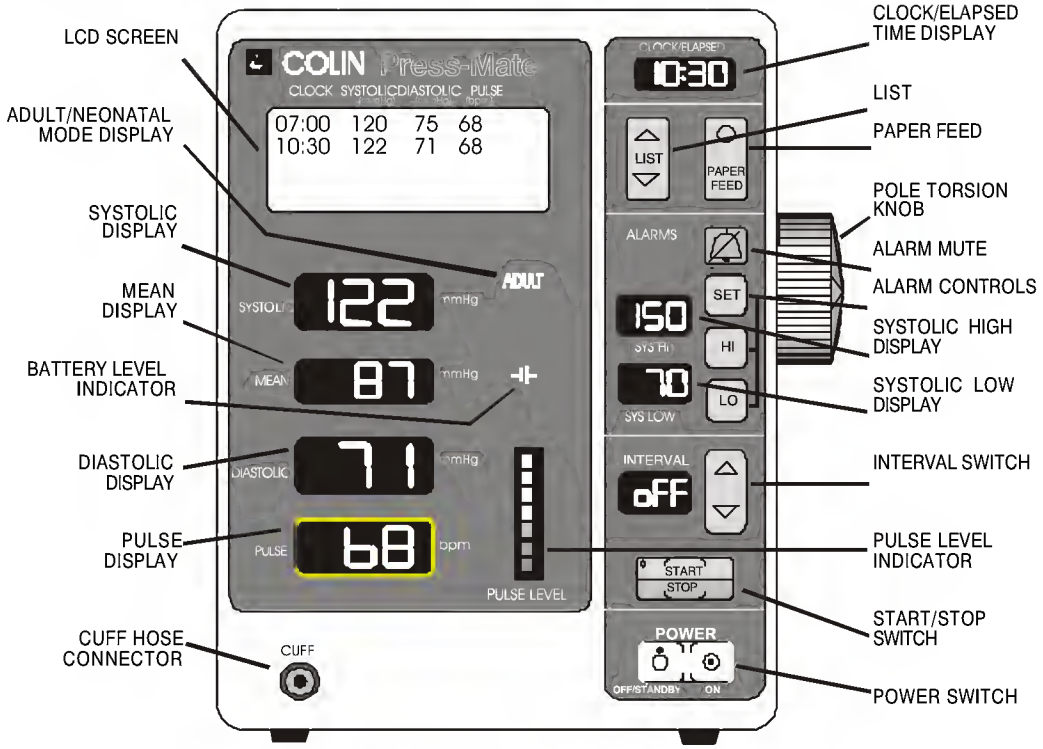
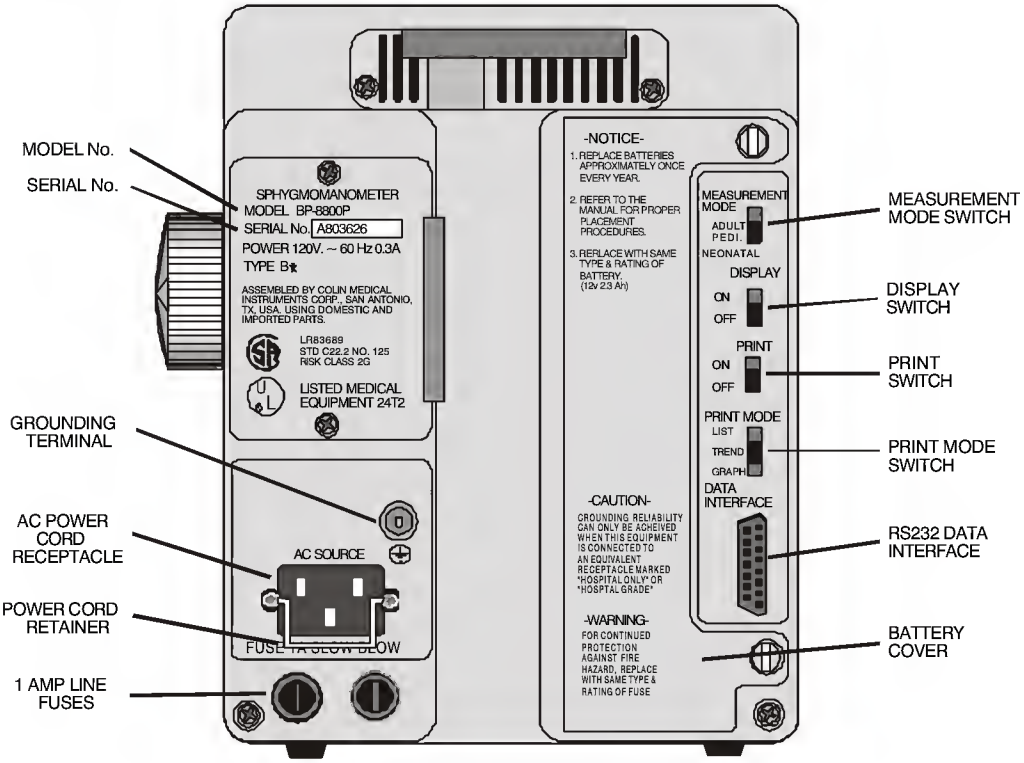
2.3 Diagrams

Front Panel 8800/P



Back Panel 8800/P



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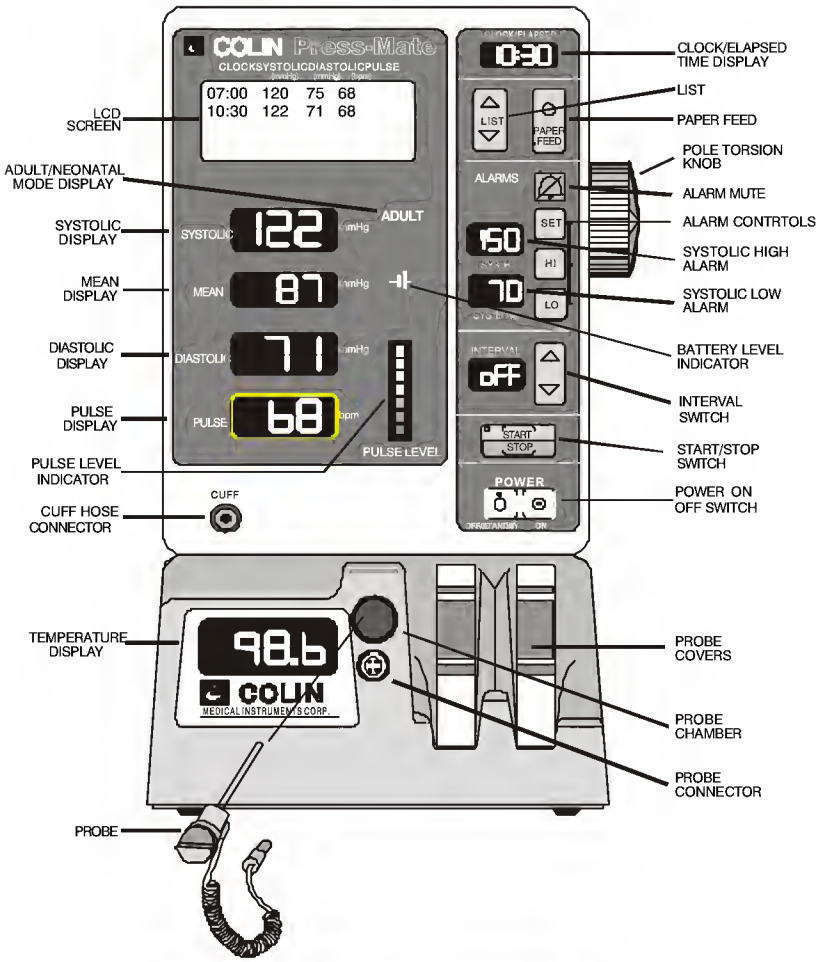
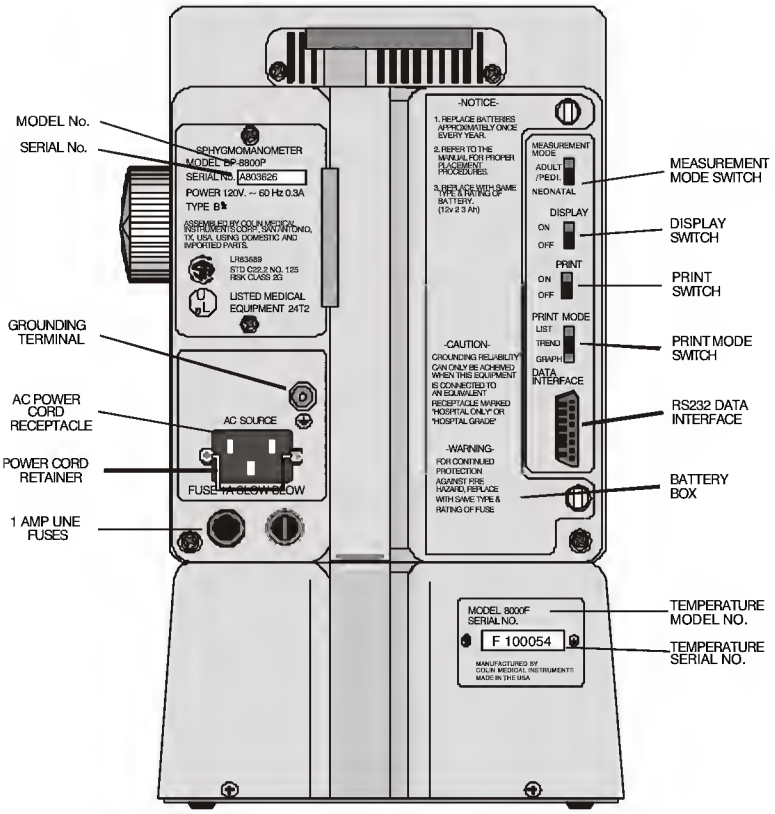
Front Panel 8800F/FP



Back Panel 8800F/FP



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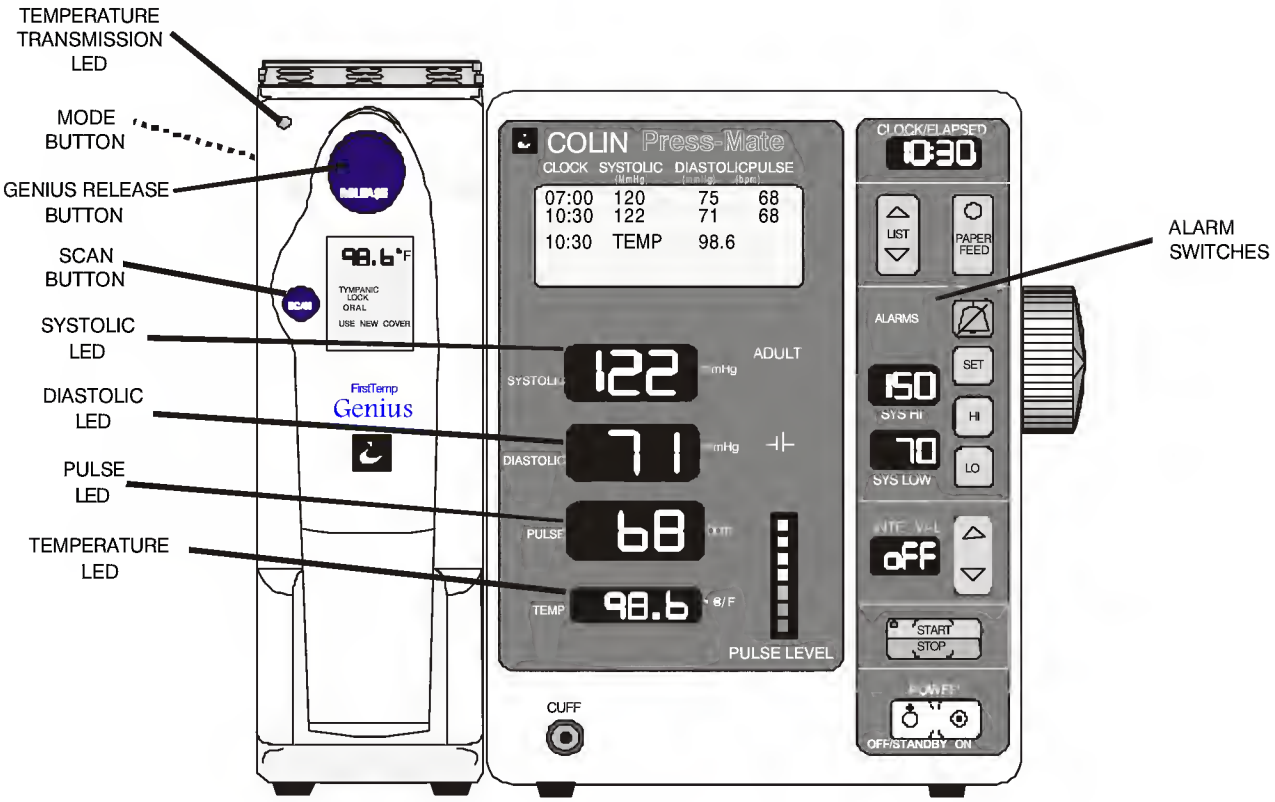
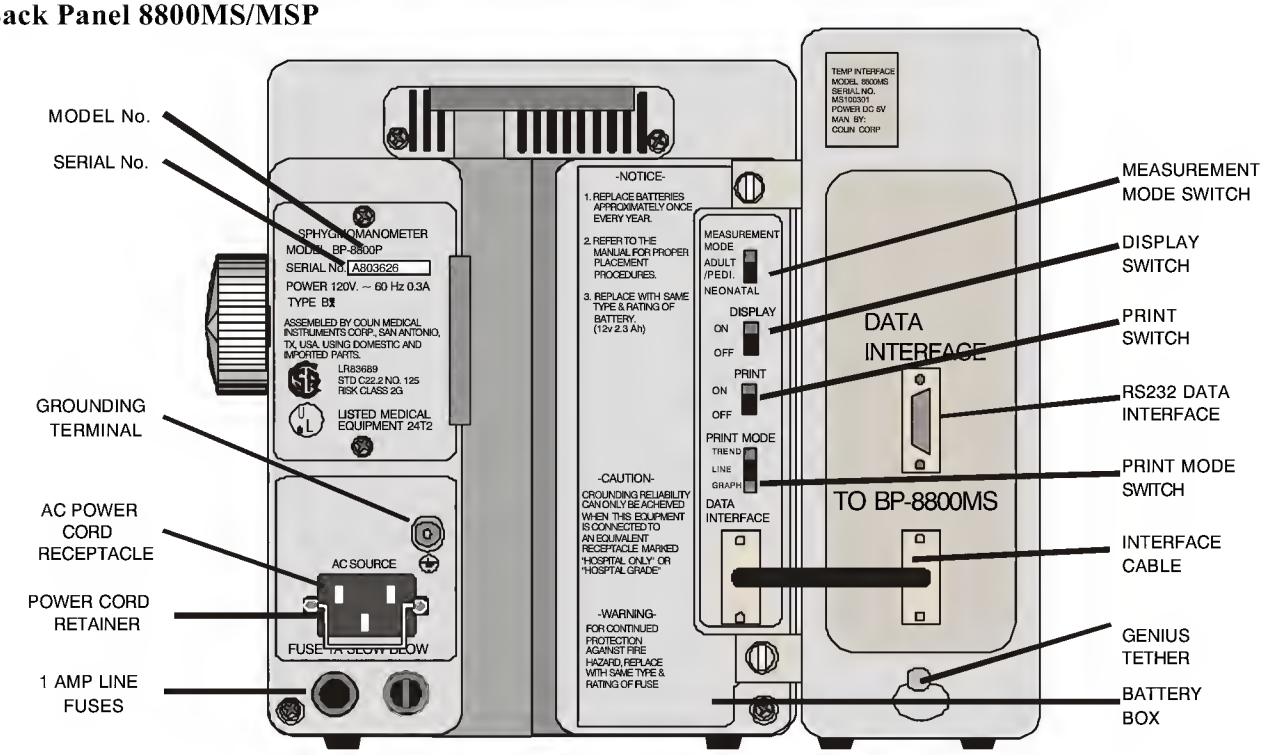
Front Panel 8800MS/MSP



Back Panel 8800MS/MSP



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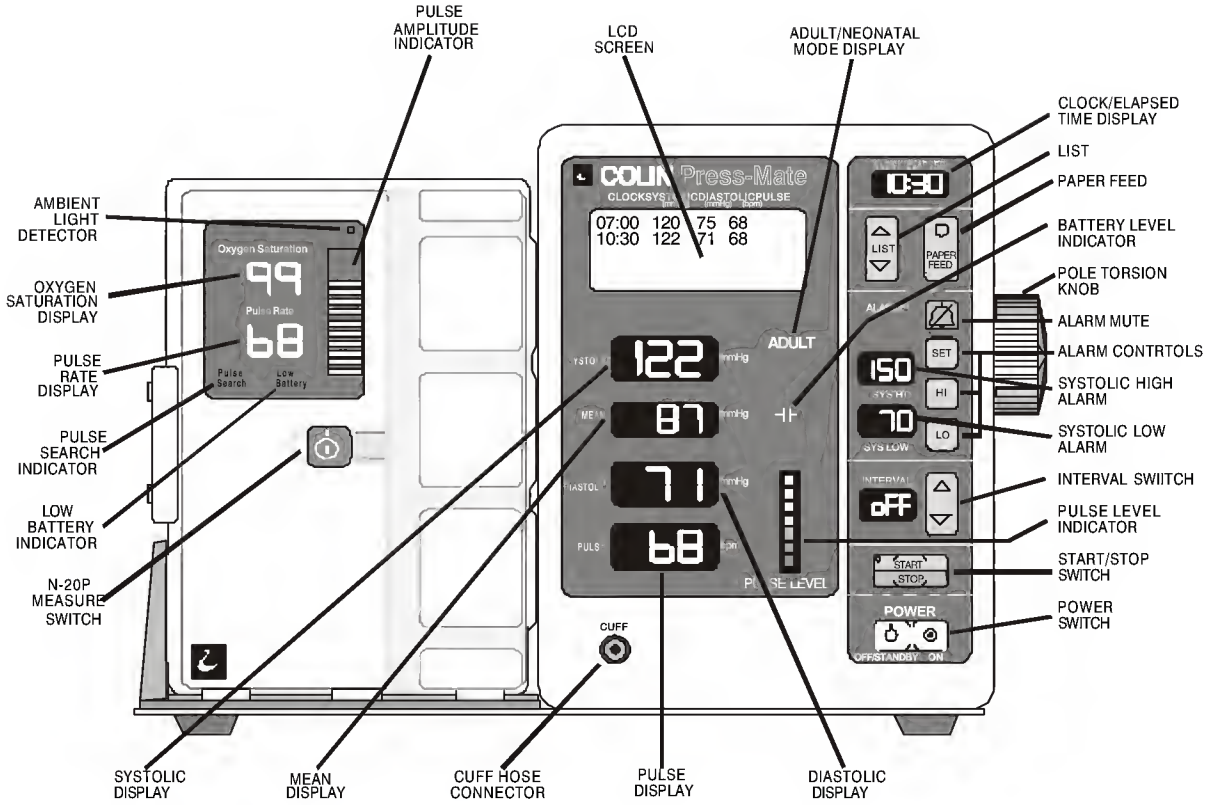
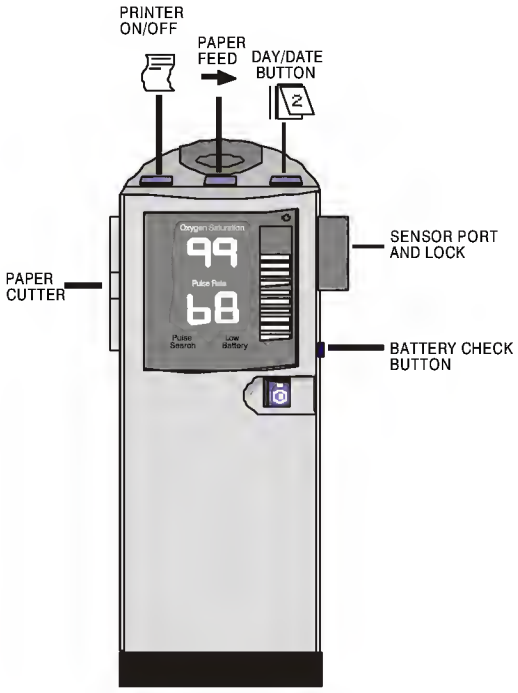
Front Panel 8800SAT/SATP





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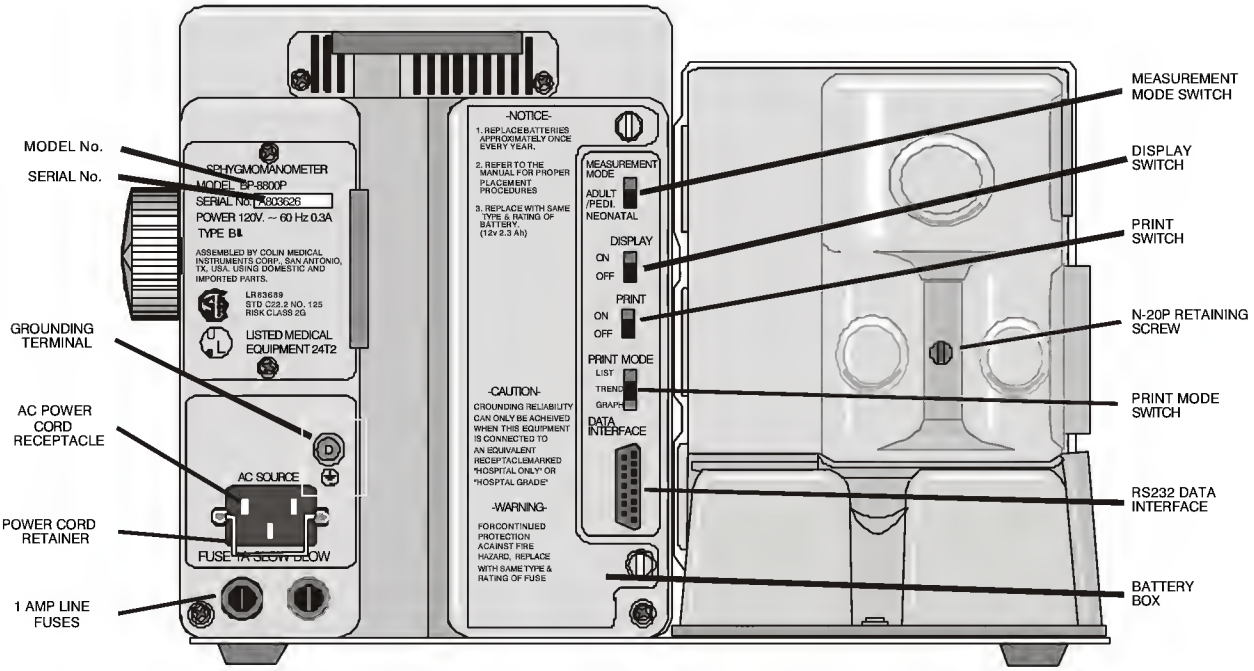
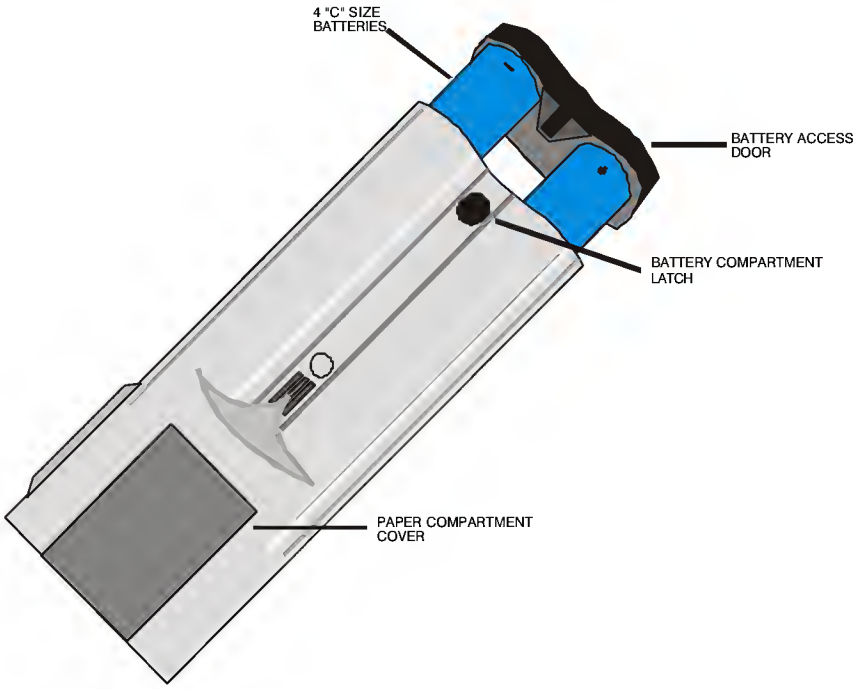
Rear Panel 8800SAT/SATP





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3.0 Installation

3.1 Precautionary Statements

- The Press-Mate's accuracy is dependent upon the application of the proper cuff and hose.
- The monitor will not operate efficiently on patients who are experiencing convulsions or tremors.
- If the cuff is not at heart level, the reading may be affected by hydrostatic effect.
- The Press-Mate should not be used on patients who are linked to heart/lung machines.
- To obtain accurate determinations, extremity and cuff motion, as well as the patient's speech, must be minimized.
- Observe the patient's cuffed extremity for signs of impeded blood flow when monitoring at frequent intervals.
- Read and observe all the caution and warning labels affixed to the Press-Mate monitor.
- Arrange the power cord and pneumatic hoses carefully so that they do not constitute a hazard.
- Connect to suitable AC power source for 24 hours before use.
- Place Press-Mate on firm base or mount securely on heavy-duty stand. Do not place anything on top of the monitor.
- Avoid spills by using the protective vinyl cover.
- Do not use in the presence of flammable anesthetics.
- Arrange power cord and cuff hose so they do not create a hazard or get bumped during use.
- Use the correct size cuff and proper wrapping techniques.
- Always press front panel switches with finger tip; not a finger nail or pointed object.
- Clean the unit with a soft damp cloth. Do not use solvents or other harsh chemicals to clean. Do not autoclave or submerge unit in sterilant.
- Possible fire hazard when used with oxygen administering equipment.
- Cover may only be removed by qualified service personnel, due to possible shock hazard.

Additional Precautionary Statements for the 8800SAT/SATP

- The N-20P is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Shock hazard. Cover of the N-20PA Pulse Oximeter to be removed by qualified personnel. There are no user-serviceable parts inside.
- Do not use the N-20P or oximetry sensors during magnetic resonance imaging (MRI) scanning.
- Conducted current could potentially cause burns. Also, the N-20PA Pulse Oximeter may affect the MRI image, and the MRI unit may affect oximeter accuracy.
- To avoid possible patient strangulation with the sensor extension cable, it is important that a health care professional remain with the patient at all times during use of the N-20PA Pulse Oximeter.

- Use only Nellcor® oxygen transducers. Use of other oxygen transducers may cause improper oximeter performance.
- Inaccurate measurements may be caused by incorrect sensor application or use; significant levels of dysfunctional hemoglobin or intravascular dyes; exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared head lamps or direct sunlight; excessive movement; venous pulsations; electrosurgical interference; and placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Remove batteries from the N-20P during prolonged storage.
- To clean the N-20PA Pulse Oximeter, dampen a cloth with a commercial, nonabrasive cleaner, and lightly wipe the surfaces of the N-20PA. Do not spray or pour liquid on the instrument or accessories. Do not allow liquid to contact connectors, switches, or openings in the chassis.

Additional Precautionary Statements for the 8800F/FP

- Cleaning the thermometer may be done by wiping the exterior casing of the thermometer unit and the probe with an alcohol solution. Use a cloth or sponge, just damp, not wet, and avoid getting any liquid into the interior of the thermometer.
- The thermometer may be gas (ethylene oxide) sterilized. Do not sterilize with dry heat or autoclave. Refer unit to Biomedical Engineering.
- When not in use, store the thermometer probe in its protective chamber located in the thermometer unit beneath the blood pressure monitor.

Additional Precautionary Statements for the 8800MS/MSP

- Always use a new probe cover. Soiled covers will affect accuracy.
- Genius should not be used on patients with profuse ear drainage or the presence of blood or cerebrospinal fluid in the ear canal.
- In the unlikely event of a perforation in the probe cover membrane, accuracy may be affected. Visually inspect probe cover prior to taking a temperature.

DANGER! Oxygen vigorously accelerates combustion. Possible fire hazard may occur with the N-20PA Oximeter when used with oxygen administering equipment. Explosion hazard when used in the presence of flammable anesthetics.

3.2 Installation

1. On the rear panel, turn the printer switch to the "ON" position and the display switch to the "ON" position.
2. Connect the pressure hose securely to the connector on the front panel of the monitor.
3. Select the proper size cuff and attach securely to the air hose.
4. To measure using the battery power, check that the front panel battery indicator is lit and green. To measure using AC power, connect the three-pronged power cord into the receptacle on the rear of the unit.
5. If your Press-Mate includes a built-in printer, load the paper by following the instruction on the side panel of the monitor or refer to Section 5 of this manual.

6. Press the power switch located in the lower right hand corner of the front panel of the monitor. All LED's will light up and "SELF-TEST" and the Press-Mate's current software revision will be displayed on the LCD list screen. There will be three (3) beeping sounds at this time.

7. The blood pressure measurement operation can be started when "0" is displayed in the mean window.

NOTE: On the MS Series units, "0" will be displayed in the diastolic window. Note that the temperature on the 8800FP displays is always off when the thermometer probe is in the probe chamber.

8. Install one or two packages of probe covers in the holder located on top of the Temp-Mate for 8800MS, and next to the temperature LED display on the 8800F.

9. 8800MS: Attach tether from Genius to Temp-Mate.

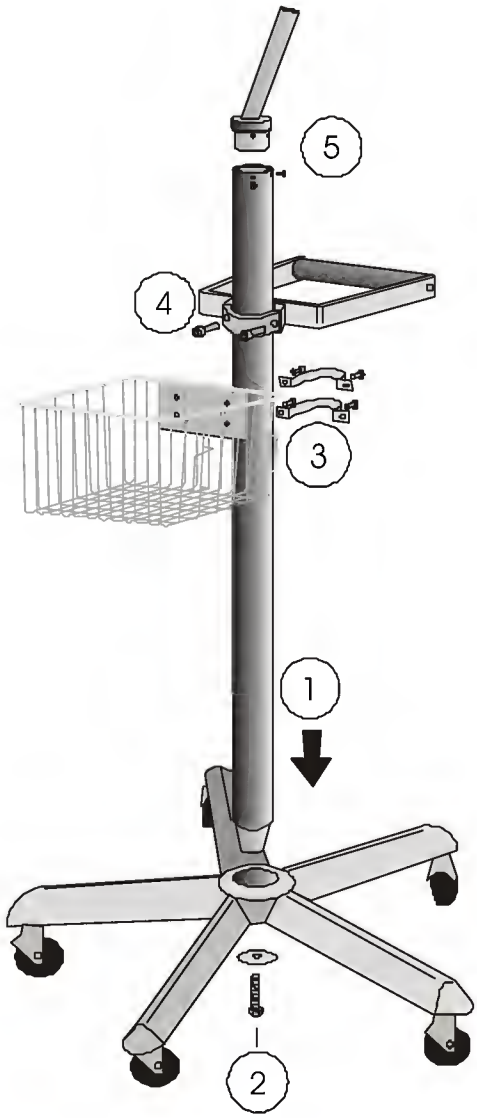
10. 8800SAT: Confirm the unit has adequate battery power. To check the level of charge remaining in the battery, with the N-20P turned on, hold the battery check button down for 2 seconds. The percentage of lighted segments in the pulse amplitude indicator approximates the battery charge: all segments light with fully charged batteries. If the batteries need to be replaced refer to section 4.

11. 8800SAT: Verify proper clock setting on N-20P.

12. 8800SAT: Connect the sensor cable into the sensor port on the N-20P, close the sensor lock over the connector, connect the appropriate sensor to the cable and attach the sensor to the patient as described in the operation manual.

3.3 Stand Assembly

1. Slide the roll stand post through the center hole of the base.
2. Tighten the base bolt through the flat washer to secure the roll stand post.
3. Slide basket onto roll stand post and tighten basket screws when basket is at the desired level.
4. Attach handle to roll stand post with handle ring and screws.
5. Attach Press-Mate mount to roll stand post. The mount type may vary from picture depending upon model.



NOTE: Stands with a 12 degree post need two screws to be inserted through the pole to secure the post.

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3.4 Cuff Placement

Proper cuff size and placement is essential to assure accurate blood pressure measurement.

The American Heart Association recommends cuff sizes should be at a length to width ratio of about 2:1, ensuring that if the bladder width is 40 percent the arm circumference, the bladder length will encircle 80 percent of the arm.

Below, in Figure 2.1, bladder width is small for arm, and full cuff pressure is never applied to artery. An erroneously high pressure results. Below, in Figure 2.2, bladder width is adequate for arm, and full cuff pressure is applied to brachial artery.

Cuffs for the thigh are available for large patients or those where neither arm is available for cuff placement. Blood pressure measured at the thigh is typically 20 - 30 mmHg higher than blood pressure measured at the upper arm.

Source: American Heart Association

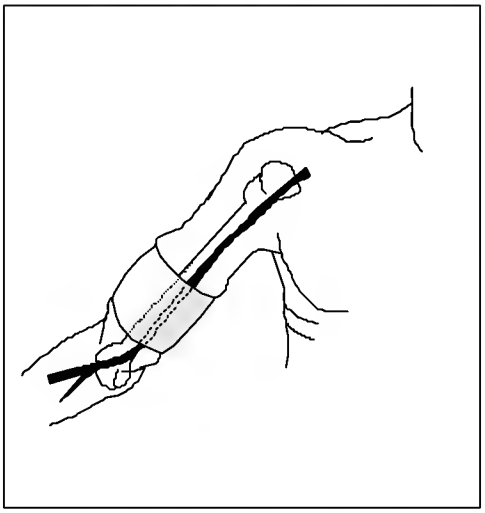


Figure 2.1

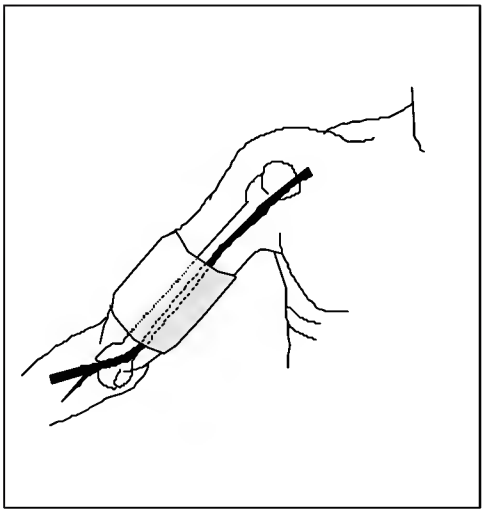


Figure 2.2

Wrap the cuff in the following way:

Wrap the cuff snugly with room between the cuff and the arm for two fingers. If the cuff is wrapped too loose, it cannot be inflated properly and there may be errors in measured values.

It is best to wrap a bare arm; clothing may cause errors in measured values.

The end of the cuff should fall inside the range marked clearly on the inside of the cuff. If it doesn't, a different size cuff should be used. (See Figure 2.3)

The artery mark on the center of the cuff bladder should be placed over the brachial artery, and make sure not to twist, kink, or otherwise occlude the hose.

Keep the cuffed part of the arm at the same level as the heart (See Figure 2.4)

If it is above the level of the heart, the blood pressure measurement may be lower than actual. If it is below the heart level, the blood pressure may be higher than actual (due to the physical weight of the blood).

Do not compress the cuff or the rubber cuff hose.

> **Note:** Compression of the cuff or the cuff hose may cause measurement error.

The patient should remain still and quiet during the blood pressure measurement.

Figure 2.3

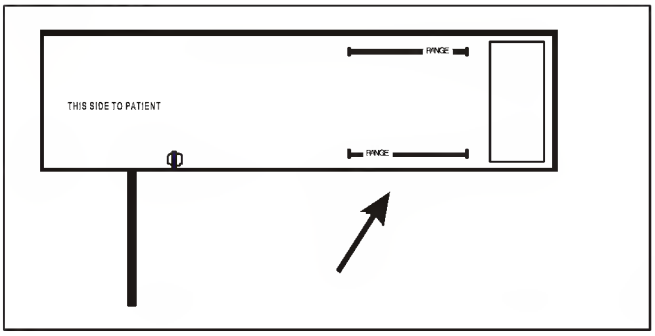
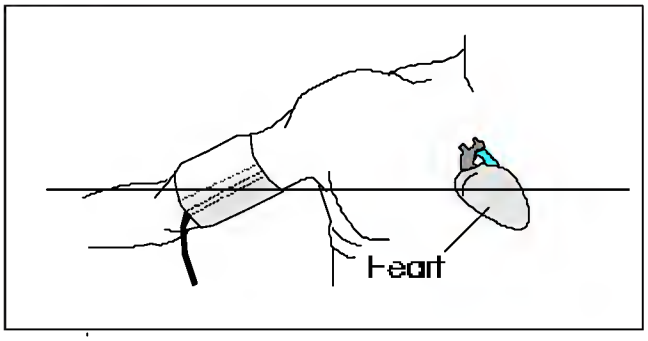


Figure 2.4



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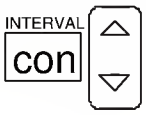
4.0 Special Control Settings

4.1 Setting the Blood Pressure Measurement Interval

Measurement is initiated automatically at timed intervals by pressing the "INTERVAL" switch.

Press the switch to display a value on the "INTERVAL" display sections. 

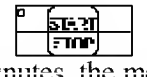
INTERVAL Settings (minutes):
OFF, CON, 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, 90, 120, 180

When the interval is selected, cuff inflation will begin immediately after depressing the

button.

After the measurement is completed, it will be repeated at the specified interval.

> **Note:** If an interval of 1 minute is selected, after 12 measurements, the monitor will automatically change its interval measurement to 5 minutes.

Consecutive measurements are started when "CON" is specified and the  button is pressed. Consecutive measurements are taken for a period of 5 minutes. After 5 minutes, the measurement interval is automatically set to 5 minutes.

For consecutive measurements, press the

button again.

To interrupt the measurement, press the

button during the measurement.

When consecutive measurements are specified, a rapid estimation of systolic blood pressure is displayed ("Quick SYS Function") as soon as it is determined, followed by measurement of diastolic blood pressure and the pulse rate.

> **Note:** In "CON" mode of operation, the value of systolic pressure may change to a new actual value after the measurement cycle has been completed.

4.2 Alarms

Audible

The monitor will sound an alarm when parameters set for systolic, mean, diastolic pressures, or pulse rate are violated. The audible alarm is a high-pitched tone that sounds at one second intervals. To silence the alarm press the switch.

> **Note:** In the Adult/Pediatric Mode, if systolic pressure drops below 70 mmHg, the alarm will sound, no matter where the limits are set.

If the monitor is unable to take a pressure due to an error code displayed in the LCD display, [Example: E03 — Cuff Disconnect] the audible alarm will sound continuously until the switch is pressed.

If the monitor is unable to determine the measurement values and a caution code is displayed in the LCD display [Example: C13 — motion artifact], three consecutive audible (alert-before-measurement-retry) tones will be sounded to announce a measurement retry.

Visual

The visual alarm will be noticed as a flashing LED display of the measurement parameter that violated the alarm setting. The LED display will remain flashing until the next measurement is taken. Even if the audible alarm is silenced, visual alarms still display as a flashing LED.

Alarm Limits

	High Limit	Low Limit
Systolic	60 - 240 (mmHg)	20 - 160 (mmHg)
Mean	60-200 (mmHg)	20-120 (mmHg)
Diastolic	50 - 180 (mmHg)	15 - 120 (mmHg)
Pulse	80 - 220 (bpm)	40 - 140 (bpm)
Temperature 8800MS/8800MSP (only)	85.0 - 99.0 ^{0}F	97.0 - 107.0 ^{0}F

Setting Alarm Limits

Press the "Alarm Set" SET switch. The LCD display shows the menu and the cursor flashes at "SYS".

Set the upper and lower limits for "SYS". Press the SET switch to set the upper limits (the value cannot be set below the lower limit on the alarm setting).

Press the LO switch to set the lower limits (the value cannot be set higher than the upper limits on the alarm setting).

Press the SET switch again and systolic alarm limits are set.

Every time the SET switch is pressed, the flashing indicator on the LCD display moves to the next parameter: "MBP" (mean blood pressure), "DIA", and "PR" respectively. Set the upper and lower limits for each indicator in the same way as in Step 2, 3, and 4.

Press the SET switch one last time to exit the alarm menu. Once the alarm limits have been set, they will not change, even when the power is turned off.

> **Caution:** When the measured value reaches or exceeds the high limit or falls below the low limit settings, its display will flash continuously. If the audible alarm has been set and a violation has occurred, the audible alarm will sound continuously.

4.3 Setting the Clock

The clock, initial inflation pressure and special alarm features can be easily set to fit specific clinical needs. Once the values are set, they will not change, even when the unit is turned off.

Turn unit off. Hold down the START STOP switch and the ON switch at the same time. Release when the clock menu is displayed on the LCD screen.

Press the START STOP switch to scroll the flashing cursor to the year, month, day, hour, and minute. Set correct time and date by pressing the LIST switch up or down arrows.

> **Note:** Time is displayed on the 24-hour system.

4.4 Alarm ON/OFF

Press the

switch until the cursor reaches the alarm buzzer. When alarm is set to “ON”, the alarm tone will sound continuously until the switch is pressed. The alarm tone is preset to “ON” at the time of shipment from the factory. When the alarm tone is not required, set it to “OFF”. When the alarm tone is “OFF”, the LED of the measured parameter which violated the alarm settings will still flash and the systolic "HI" and "LO" LEDs will show "ALb OFF".

4.5 Initial Cuff Inflation Value

Press the

switch until the cursor reaches initial inflation. Set initial cuff inflation pressure value by pressing the

switch up or down. In the adult/pediatric mode, the value can range from 120 mmHg to 240 mmHg in increments of 20 mmHg. In the neonate mode, the value can range from 80 mmHg to 140 mmHg in increments of 20 mmHg.

4.6 Pre-Measure Tone

Press the

switch to scroll the cursor to the pre-measure tone selection. When this selection is "ON", the monitor will give notification of an oncoming Timed Interval Measurement. Two short beeps will sound 10 seconds prior to the measurement to allow the patient to become prepared for the measurement.

4.7 Smart Monitoring

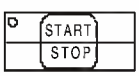
Press the

switch to select the Smart Monitoring feature. If "OFF" is selected, the Smart Monitoring feature will not activate. If "1" is selected, the monitor will complete a blood pressure change verification once between interval measurement. If "3" is selected three verifications will be made between interval measurements.

Note: The Smart Monitoring feature will not activate in the Neonate Mode, and only activate if the measurement intervals are greater than 5 minutes in the Adult Mode. If a noticeable blood pressure change is detected, the Smart Monitoring feature will automatically initiate a blood pressure measurement.

Note: The Smart Inflation feature will only activate in the Adult Mode. If the Neonate Mode is selected, the inflation pressure automatically defaults to the initial inflation pressure setting.

4.8 Smart Inflation

Press the 

switch to select the Smart Inflation feature. If "ON" is selected, the inflation pressure will automatically be determined by the artery occlusion point during the inflation of the cuff. If "OFF" is selected, the inflation pressure will default to the initial inflation setting.

4.9 Alarm BP

Press the

switch to select the Alarm BP feature. If "ON" is selected, the monitor will automatically take a second blood pressure measurement upon an alarm limit violation to aid in verifying an alarm condition. If "OFF" is selected, no automatic blood pressure measurement will be taken upon an alarm limit violation.

After completing the setup procedures, turn off the front panel power switch and turn it on again. This will complete the time, initial inflation, and alarm settings.

4.10 Hemodynamic Mode

The Hemodynamic (HD) Mode allows the Press-Mate to automate the sequence of timed measurement intervals. The HD Mode allows the user to select from five interval programs. The first three programs are factory-set and the remaining two programs are user-adjustable. All of the programs once initiated can have the interval selection adjusted as needed during that time period. This allows the Press-Mate to be customized to meet any requirements needed.

To place the Press-Mate into the Hemodynamic mode, follow these instructions:

1. Open the Battery Cover on the back of the Press Mate.
2. Remove the battery from the compartment with the use of the battery removal ribbon (you will not need to disconnect the battery from the wires at this time).
3. Locate through the upper right hand corner of the battery compartment the set of eight dip switches.
4. Move number eight dip switch into the up or ON position.
5. Return the battery and cover.
6. Turn the Press-Mate ON, the monitor will automatically enter the Hemodynamic mode.

Note: If the monitor asks for a Pass Word, contact COLIN's Technical Service Dept. at 800-829 NIBP for further instructions. The Pass Word is initially input at COLIN during manufacturing, and should not be asked for again unless the internal RAM (service menu test interval 5) has been completed.

To remove the Press-Mate from the Hemodynamic mode, the number eight dip switch will need to be returned to down or OFF position.

Note: The Hemodynamic Mode cannot be used until it is activated. To activate, please refer to the Press-Mate Product Service Manual, Revision B. While the Press-Mate has the Hemodynamic Mode activated, the Smart Clock feature is deactivated.

Upon activation, the LCD will display the following:
Directional Message

HD MODE DIRECTIONS USE LIST - TO SELECT USE SET TO ENTER Press SET to continue

Screen #1

As this message shows, you must choose a selection by pressing the LIST ↑ and ↓ buttons to move the cursor, then press SET to enable that selection. Press SET now to continue to the next screen, which will appear as follows:

SELECT PROGRAM Prog: A B C D E Modify Read Program Exit to Routine Oper.

Screen #2

Interval Program Selections A, B, and C are factory set programs. Those programs are as follows:

Prog. A → Time 4.00 Hr.

Start → 1.00	@ 5 Int.	5 min. measurement intervals for one hour
1.00 → 2.00	@ 15 Int.	15 min. measurement intervals from the first hour to the second
2.00 → 4.00	@ 30 Int.	30 min. measurement intervals from the second hour to the fourth
4.00 →	@ 60 Int.	60 min. measurement intervals from fourth until manually stopped

Prog. B → Time 3.00 Hr.

Start → 1.00	@ 15 Int.	15 min. measurement intervals for one hour
1.00 → 3.00	@ 30 Int.	30 min. measurement intervals from the first hour to the third
3.00 →	@ 60 Int.	60 min. measurement intervals from the third until manually stopped

Prog. C → Time 1.00 Hr.

Start → 1.00	@ 10 Int.	10 min. measurement intervals for one hour
1.00 →	@ 30 Int.	30 min. measurement intervals from the first hour until manually stopped

Programs D and E have not been formatted so that you can create those programs in any manner you wish.

The "MODIFY PROGRAM SELECTION" of Screen #2 allows the user to view/modify the Internal Programs. The "EXIT TO ROUTINE OPERATION " selection allows the monitor to return to routine operation without its Hemodynamic Mode.

Note: If no selection is made within one minute, the monitor will exit to routine operation. No Interval Measurement will be taken until the operator initiates the first measurement, by pressing the Start/Stop button.

Caution: The monitor limits the continuous measurement to 5 minute maximum only and 12 measurements for 1 minute interval measurements. The monitor will automatically set the interval at 5 minutes after reaching the limiting time.

If a program is selected, the LCD will display the program of choice, its total running time and then await the pressing of the SET button to begin the program.

```
PROGRAM  → A
TOTAL  TIME:  4.00  HRS

Press  SET  to  begin
```

Screen #3

If MODIFY/READ PROGRAM is selected, the LCD will then display the Modify Program screen:

```
MODIFY / READ  PROGRAM
NOTICE  --  PROG.  CHANGES
ALSO  CHANGE  DEFAULTS
MODIFY  PROG.: A   B   C   D   E
```

Screen #4

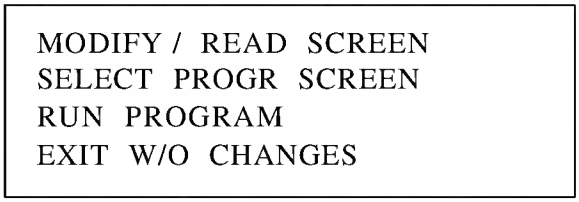
Note: Program changes also change "power-up" defaults of program.

From this screen, you can either view or modify the selected programs.

Note: Programs A, B, and C cannot be changed, they can only be viewed.

While viewing or modifying an Interval Program, the LCD is only capable of displaying four lines of data. You will need to press the SET button to advance the cursor onto the second screen of each program. Press the SET button to advance the cursor, and the LIST ↑↓ buttons to increase or decrease the selection value.

After you have completed viewing or making modifications, the LCD will then display:



Screen #5

If "MODIFY/READ SCREEN" is selected, the monitor will return to Screen #4. If the "SELECT PROGR" screen is selected, the monitor will return to Screen #2. If "RUN PROGRAM" is selected, the monitor will display Screen #3 and if "EXIT WITHOUT CHANGES" is selected, the unit will return to routine operation.

Display of HD Mode Operation:
Once a program has been initialized, the monitor will display "Hd" and the current interval time on the interval LEDs in turn to signify HD Mode operation.

End of HD Program:
Whenever the HD Program is complete, the message "HD PROGRAM END" will be displayed on the LCD screen.

Changing the interval during an HD Program Measurement:
Whenever a change in program is needed, you can press the INTERVAL ↑ and ↓ button to change the current period interval selection.

Note: The next measurement occurs in the time interval selected (No Smart Clock). If you have chosen a continuous measurement, you will need to press START/STOP button to begin the measurement.

4.11 Printer Function

Models 8800P, 8800GP, 8800FP, 8800SATP

With the "PRINT" switch on the rear panel in the "ON" position, the monitor will automatically print after each blood pressure measurement. If you prefer, you may cancel this feature by setting the printer select switch on the rear panel to "OFF". An alarm violation will automatically printout an oscillometric profile even if the print switch is in the "OFF" position.

The printout format can be changed by selecting Graphic Trend (See Figure 4.1), Line List (See Figure 4.2), or Oscillometric Profile (See Figure 4.3) from the selections of the "Print Mode" switch on the rear panel.

Model 8800MSP

With the "PRINT" switch on the rear panel in the "ON" position, the monitor will automatically print after each blood pressure measurement or any alarm violation. If you prefer, you may cancel the automatic production of a print-out by setting the printer select switch on the rear panel to "OFF".

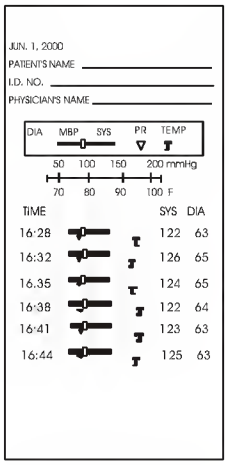


Figure 4.1

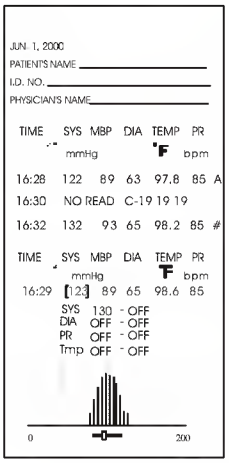


Figure 4.2

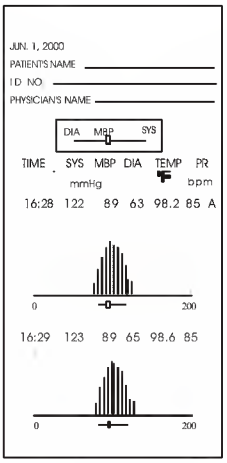


Figure 4.3

Figure 4.1 shows a trend as well as a digital printout of measurements.
The ▬ marking represents, from left to right, the diastolic, mean, and systolic blood pressure values.

Figure 4.2 shows an example of a line listing printout, an error code printout, and/or an oscillometric profile (see note below on this unique Press-Mate feature). The # in the right column indicates motion artifact while the "A" or "N" indicates either Adult/Pediatric Mode or Neonate Mode.

Figure 4.3 shows an example of an oscillometric profile printout on each measurement.

Note: This oscillation profile assists the clinician in determining the validity of the measurement that caused the alarm. An erratic or flat profile suggests that excessive motion or other artifact may have affected the measurement. A profile shaped like a bell curve represents a measurement not affected by motion or other artifact.

4.12 Loading Paper

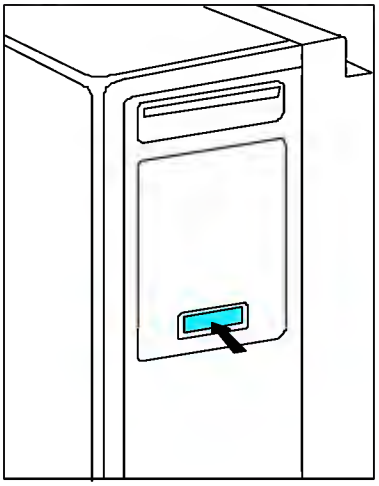


Figure 4.4

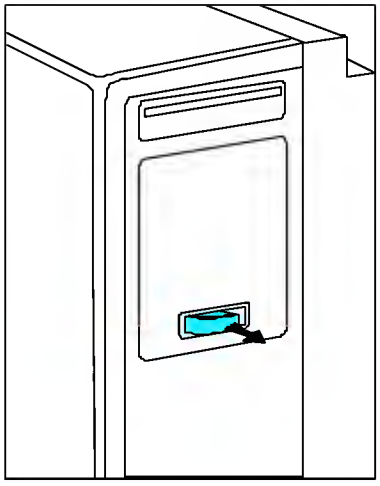


Figure 4.5

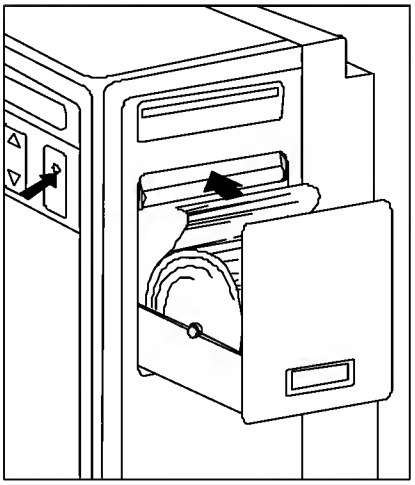


Figure 4.6

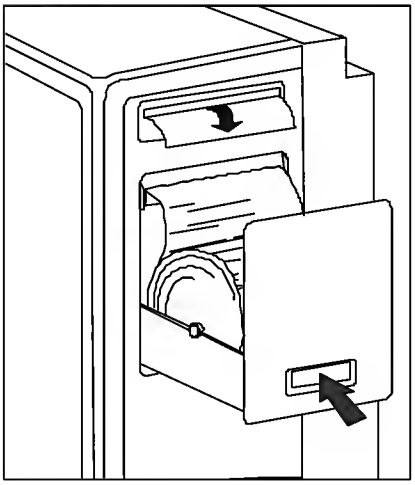


Figure 4.7

1. Press the power switch "ON".
2. Set the printer switch on the rear panel "ON".
3. Push the right end of the handle to expose it (Figure 4.4).
4. Pull the paper case out all the way (Figure 4.5).
5. Insert a fresh roll of paper in the paper case. The Press-Mate uses thermal recorder paper. Take care to insert properly; see instructions on side of unit for more details.
6. Feed an inch or so of paper through the printer rollers by pressing the Paper Feed switch (Figure 4.6).
7. Replace paper case and handle (Figure 4.7).

5.0 Special Features

5.1 Memory

The Press-Mate can store up to 400 blood pressure measurements in memory. The last four measurements are displayed on the LCD list screen. When more than four data items are stored, the ↑ mark is displayed on the right hand side of the LCD screen.

Data is scrolled up by pressing the up arrow △ LIST on the

switch and scrolled down by pressing the down arrow LIST ▽.

To clear the stored data, press and hold the two LIST ▽ △ LIST switches simultaneously. "MEMORY CLEAR" will be displayed on the LCD screen and the listed data will disappear.

> **Note:** The listed data is stored for 10 minutes after the power is turned off.

Printing the Memory

To print the data that is stored in memory, press the down arrow LIST ▽ on the

switch until the beep tones stop and the following message appears:

PRESS START/STOP
SWITCH TO PRINT
MEMORY LISTING
USE LIST - ▽ TO CANCEL

Press the

switch and the printout will begin. The LCD will now display "ALL DATA PRINTED".

To interrupt the printing at any time, press the LIST ▽ switch again.

5.2 Clock/Elapsed Time Meter

COLIN'S clock is a smart clock. Interval cycling of blood pressure measurements is coordinated with logical clock time. For example, during 15 minute measurement intervals that begin at 10:07, the next measurement will be at 10:15, then 10:30, 10:45, and so on.

> **Note:** The smart clock feature is disabled while using the Hemodynamic Mode option.

An elapsed time meter alternates with the clock time to let you know how many minutes it has been since the last measurement.

5.3 Quick Systolic — Consecutive Measurements

Consecutive blood pressure measurements can be made for five minutes. To avoid possible patient discomfort, after five minutes of consecutive measurements the monitor automatically resets itself to five minute measurement intervals.

When interval timing is set to "CON", a quick estimation of systolic blood pressure is displayed within 12 seconds. This value is then updated as soon as the diastolic pressure is determined.

5.4 Neonatal Mode

To use the Press-Mate on neonatal patients, follow these guidelines:

1. Set the rear panel MEASUREMENT MODE switch to 'NEONATE".

2. Connect the green colored pressure hose and COLIN's disposable neonate blood pressure cuff to the monitor and patient.

3. Standard initial inflation pressure in the neonatal mode is 120mmHg.

LCD Screen
Displays data for previous four (4) measurements; maximum of 400 lines of memory can be scrolled. Alarm limits and error codes are also displayed on this screen.

Adult/Neonatal
Displays which mode the monitor is in, adult/pediatric or neonatal.

5.5 Blank Display

The front panel displays may be blanked so that patients cannot view their blood pressure values. Set the rear panel DISPLAY switch to "OFF". The cuff pressure will still be displayed in the Mean LED (Diastolic for 8800MS/MSP) window as the unit inflates.

5.6 Operation: Genius

The Press-Mate 8800G and 8800MS have the First Temp Genius Model 8300G Tympanic Thermometer attached via the Temp-Mate. The Genius is simple to use and usually measure the patient's temperature in less than two (2) seconds. Refer to the following instructions to operate the Genius:

1. Tympanic Temperature Measurement

a. Grasp and pull the Genius from the Temp-Mate.

b. Note the mode setting (TYMPANIC, or TIMER) on the Genius display. If the mode setting is not TYMPANIC, press and release the MODE button on the underside of the Genius until TYMPANIC is displayed.

c. Note the units of measurement, displayed in either degrees Fahrenheit or Celsius. If the unit displayed is not the desired unit of measure, press and hold the MODE button on the underside of the Genius until the desired unit is displayed.

d. The equivalence should be displayed as CORE, REC, or ORAL. This means the tympanic temperature measured will be automatically converted to the correct equivalent temperature. If CAL is displayed, change the equivalence as described in Section 4.

e. Place a disposable probe cover on the probe tip. The probe covers are located in the patient pack on the top of the Temp-Mate.

f. Place the probe in the ear canal just far enough to seal the opening. If necessary, gently restrain the patient's head movements while taking his or her temperature. In infants or other patients in which the probe tip cannot enter the out ear canal, SEAL THE OUTER OPENING with the probe tip while gently pressing the SCAN button.

g. Press and release the SCAN button. After the measurement is complete, three short beeps will sound.

h. After the triple beep, the Genius display flashes "DONE". Remove the probe from the patient's ear.

i. Press the RELEASE button to discard the probe cover.

j. Return the probe to the Temp-Mate making sure that the Genius snaps securely in place. When the temperature value has been communicated to the Press-Mate, the amber LED on the Temp-Mate will flash and a short beep will sound. The measured temperature will then be displayed int he Press-Mate TEMP LED window and the list LCD window.

k. After the value has been read by the Press-Mate, the Genius is ready for another measurement.

NOTE: COLIN has installed an Anti-Theft feature in the Genius with Software version 2.0 or lower. If a temperature measurement is attempted without the previous measurement being transmitted to the Press-Mate, the Genius will display "bP" for the measured temperature. This indicated that the value must be transmitted to the blood pressure monitor before a subsequent temperature measurement can occur.

NOTE: If the Genius is left out of the Temp-Mate for more than one minute after taking a temperature, it enters a power saving SLEEP mode. If the display says "USE NEW COVER" even though one is installed, press the RELEASE button and reinstall the probe cover to take the next temperature.

2. Setting the Equivalence

Before tympanic thermometry, clinical temperatures were measured orally, rectally, or in special cases, with an indwelling Swan-Ganz catheter. If a patient's temperature was measured simultaneously with each of these methods, three different absolute temperatures would be determined. Based on clinical studies, the Genius compensates for the average difference in temperature at each of these sites. When int he Tympanic mode, the Genius will adjust its reading to a user-selected equivalence based on statistical differences. The following equivalences are available on the Genius:

a. CAL: In the CAL mode, the display will indicate the absolute temperature without adjustment. This mode should only be used for calibration purposes. Call your COLIN Service Representative for calibration procedures.

b. ORAL: The tympanic temperature is adjusted to display an oral temperature equivalent.

c. REC: The tympanic temperature is adjusted to display a rectal temperature equivalent.

d. CORE: The tympanic temperature is adjusted to display a core temperature equivalence.

3. The equivalence may be set using the following method:

a. Remove the single screw and door on the underside of the Genius.

b. Move the RELEASE button up and down once.

NOTE: all adjustments to the microswitch panel must be preceded by moving the RELEASE button up and down once.

c. Switch 3 is the EQUIV switch. When EQUIV is in the right-hand position (NORM), the equivalence setting (displayed on the Genius LCD when in TYMPANIC mode) is locked and cannot be changed. To change the equivalence setting, first place the Genius in TYMPANIC mode, then move dip switch 3 to the left-hand position and press the MODE button to cycle throughout the setting, CAL, ORAL, RECTAL, and CORE. When the appropriate equivalence setting is displayed, return switch 3 to the right-hand position to lock-in the equivalence value.

NOTE: All other switches are set at the factory and should not be changed.

5.7 Operation: FILAC

Oral Temperatures

1. Place the probe tip firmly in the sublingual pocket on the left or right side of the frenulum linguae the vertical fold of tissue in the middle of the tongue. Aim the probe tip toward the back of the mouth.

> **NOTE**: Accurate temperatures can only be obtained in the "heat pocket" at this location. Temperatures in other locations in the mouth may vary by 2°F (1°C) or more. Hold the probe steady in this location. If the patient cannot hold it, you should. The patient's mouth must be closed for the measurement. The thermometer reading will begin to flash, then will indicate the rising temperature as the measurement proceeds.

2. The display will stop flashing and a short "beep" (optional) will sound when the final temperature has been reached. The final reading will be displayed for approximately three minutes or until the probe is replaced into the thermometer.

3. Remove the probe from the patient's mouth and discard the used probe cover by pressing on the button on the probe handle.

4. After recording the patient's temperature, replace the probe in the thermometer. Wait at least 60 seconds before taking another temperature.

Rectal Temperatures

1. Use a RED rectal probe assembly. Install a probe cover as instructed for oral temperatures, and insert the probe into the patient's rectum. To ensure proper tissue contact, angle the probe slightly to the side after insertion. Insertion depth is recommended at 1/2" - 3/4" (13-20 mm) for adults and 1/4" - 1/2" (7-13 mm) for children. A lubricant may be used, if desired.

   The measurement will proceed similarly to the oral measurement, and the final reading will be displayed when the display stops flashing and the buzzer "beeps" (optional).

Auxiliary Temperatures

1. Using the RED rectal probe, install a new probe cover in the normal manner. Have the patient raise their arm and place the probe tip on the axilla, pressing gently against the skin to ensure good contact.

2. Have the patient lower their arm and hold the probe tip in position, almost parallel to the arm. The measurement will proceed similarly to the oral measurement, and the final reading will be displayed when the display stops flashing and the buzzer "beeps" (optional).

> **NOTE**: It is important that the tip of the probe does not come into contact with a heat source like the hands or fingers prior to taking a temperature. If this should happen simply allow five seconds to elapse for the top to cool before proceeding with measuring the temperature.
>
> **NOTE**: The thermometer will turn itself off about three minutes after it is turned on, or when the probe is returned to the thermometer. Always store the probe in the thermometer, or disconnect the thermometer completely to obtain maximum battery life.

Normal/Direct Read Mode Selection

The F-2000 may be used in the Normal (NORM) or Direct (DIR) mode. The mode selected is determined by the position of the switch next to the battery compartment door on the back of the thermometer.

NORM: The F-2000 measures temperatures in approximately 30 to 35 seconds using a "predictive method".

DIR: The F-2000 operates as a temperature monitor, taking about three to five minutes to come to equilibrium and report patient temperature. An indicator LED will light in the upper left portion of the temperature display to indicate that the direct mode is selected. In DIR mode, the F-2000 can be used for long-term temperature monitoring.

5.8 Battery Care, Installation and Removal

Continuous operating time using battery power is approximately from 4 to 6 hours when the interval time is set to 5 minutes, the adult/pediatric cuff is used, and the printer is on.

Before the battery is completely discharged, the following two visual warnings will occur:

"CHARGE BATTERY" is displayed on the LCD screen.
Battery mark on the front panel ⊣|⊢ begins to flash in red.

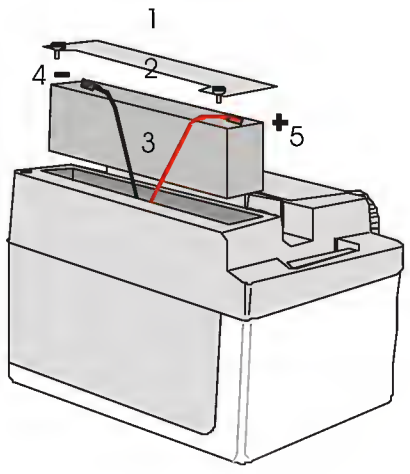
Also, when battery charge is low, the printer function will cease (to conserve energy).

If the monitor's operation is continued on battery power, the following message will appear -- "Battery Is Empty Connect A/C Plug and Power On Again" -- and the unit will shut off all power. The A/C plug will need to be attached to the unit and connected to an A/C wall outlet. To turn the unit back on, the user must press the "OFF" switch to reset the microprocessor, then press the "ON" switch. The monitor is then ready to be used.

The battery is charging any time the A/C power cord is connected to a functional A/C power source. It takes approximately 24 hours to fully charge the battery. (The "ON/OFF" switch on the front panel does not affect the battery charge.)

To replace the batteries, remove the six 4 x 1/2 screws securing the inner support to the base unit of the F-2000. Lift the inner support out of the base unit exposing the F-2000.

Remove the F-2000 from the base unit, then pull open compartment door. Swing the battery compartment door down from the top of the case. Replace the batteries with two AA cell batteries, observing the polarity on the battery compartment door. Close the battery compartment door. For maximum run-time, use only alkaline batteries.



1 Screws
2 Battery Cover Plate
3 Battery Pack
4 + Lead Wire (Red)
5 − Lead Wire (Black)

Figure 5.1 Press-Mate Battery Replacement

5.9 Procedure for Changing the Press-Mate Battery Charging Circuit

NOTE: THE PROCEDURE SHOULD ONLY BE APPLIED TO MONITORS THAT ARE BEING USED IN AREAS OF THE HOSPITAL THAT CONTINUOUSLY USE THE MONITOR ON BATTERY POWER. IF THIS CHANGE IS APPLIED TO THOSE UNITS THAT ARE NOT CONTINUOUSLY USED ON BATTERY POWER, THE OVERALL 2 YEAR EXPECTED LIFE MAY BE SHORTENED DUE TO THE CONTINUED CYCLIC CHARGING RATE.

EQUIPMENT REQUIRED:

Soldering Iron
#2 Phillips Screw Driver
Wire Strippers
Diagonal Cutters
Glue gun if shrink tubbing not available
Pot Trimmer (small long flatblade screwdriver)
DVM
Razor knife

PARTS REQUIRED:

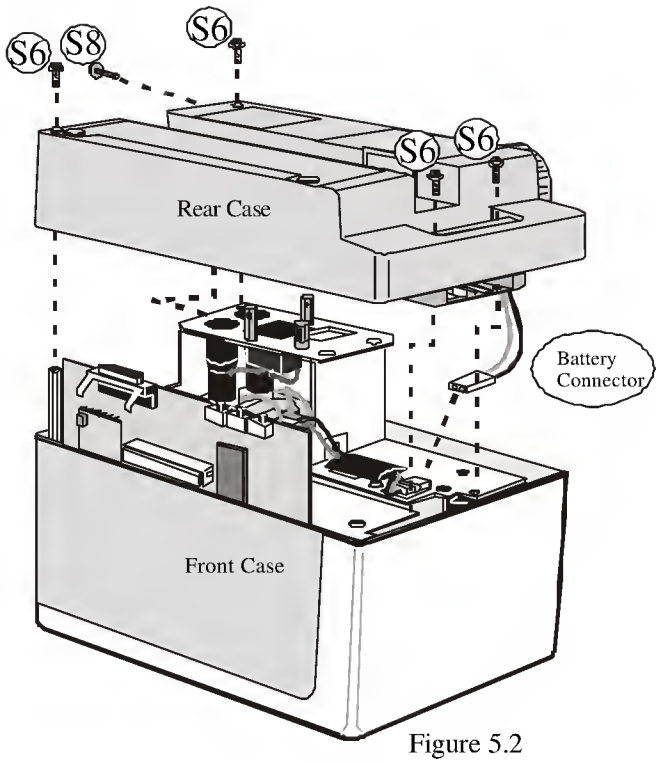
Solder
1.2" ID shrink tubbing (3" in length)
Hot glue stick if shrink tubbing not available
Small piece of 20 gauge copper wire
4" Zip tie wrap

STEPS: (about 8-10 minutes required)

1. Remove the rear case of the Press-Mate. Remove the four (S6) silver pan head screws on the rear of the unit and the S8 bronze pan head screw found on the bottom of the rear case. Lift the case and disconnect the battery connector from the chassis. Set the rear case aside. Refer to Figure 5.2 on the following page for assistance.
2. Cut the retaining zip tie to remove the battery charging circuit from the chassis. Cut the existing shrink tubbing from the circuit.

Note: If shrink tubbing is not available- Cut the lower right corner of the battery charging circuit's shrink tubing, fold the flap out of the way. Refer to Figure 5.3 on the following page for assistance in the following steps.

3. Cut and strip a ½" section of the wire and bend it into a U shape. Solder the wire onto the exposed diode to create a jumper.
4. With the use of the hot glue gun, adhere the flap back onto the circuit board.
5. Connect the DVM onto the battery connector at the rear of the chassis.
6. With the use of the pot trimming screwdriver, adjust VR1 on the power supply so that the voltage on the DVM reads between 14.5 and 14.8 VDC.
7. Connect the battery connector, and reassemble the rear case onto the monitor.



Remove the S6 and S8 screws. Lift the rear case away from the chassis, making sure to disconnect the battery connector.

When applying rear case, make sure the battery felt is located between the front case and chassis, as the rear case is lowered into position. Also verify the battery connector is appropriately connected back.

Figure 5.2

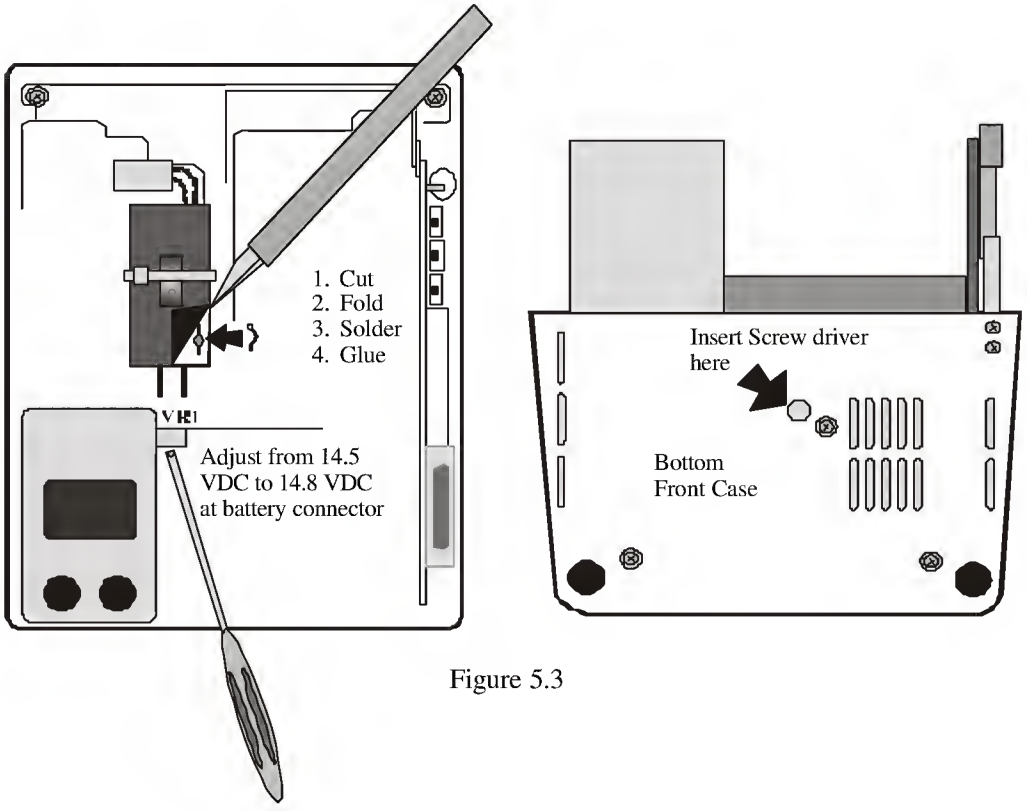


Figure 5.3

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6.0 Theory of Operation for Press-Mate, Genius and Filac

6.1 Theory of Oscillometry: Press-Mate

Oscillometry, or the oscillometric method, is a technique that may be used to automatically, non-invasively m easure blood pressure. The basic oscillometric method is relatively simple and can lead to a quick, comfortable, and reliable measurement of blood pressure. The fundamentals of the technique are easily explained.

In applying oscillometry, an inflatable cuff is placed around a limb, usually the upper arm. When the cuff is inflated and the pressure in the cuff exceeds systolic blood pressure, blood ceases to flow through the brachial artery. When the inflated cuff stops blood flow, each time the heart contracts, a very small pulse may be observed superimposed upon the cuff pressure signal. These small pulses are called oscillometric pulses.

Slowly relieving the pressure in the cuff will allow the cuff pressure to eventually become equal to the systolic blood pressure. With cuff pressure equal to the systolic blood pressure, blood can once again start to flow through the brachial artery, causing the oscillometric pulses to suddenly increase in amplitude.

If the pressure in the cuff is allowed to continue to decrease, the amplitude of the oscillometric pulses will continually increase. When cuff pressure reaches mean arterial blood pressure, the amplitude of the oscillometric pulses are at a maximum. As the pressure of the cuff is relieved, the oscillometric pulses slowly decrease in amplitude. When the cuff pressure reaches the diastolic blood pressure, the amplitude of the oscillometric pulses suddenly drops.

COLIN MEDICAL INSTRUMENTS CORP. has pioneered the development of an oscillometric technique that uses continuous linear deflation, which is similar to, but better controlled than, the manual auscultatory technique. The continuous cuff deflation technique is very comfortable for the patient, because the pressure in the cuff is being constantly relieved after the initial cuff inflation. Furthermore, COLIN has implemented algorithms in its oscillometric blood pressure monitors, which adjust the cuff deflation rate according to the patients heart rate. These special algorithms allow determination of a blood pressure measurement with maximum accuracy obtained in minimum time. This adds to the comfort of the patient.

Some measurement artifacts, such as exaggerated patient motion, arrhythmia, and hypovolemia, make any blood pressure measurement impossible. However, COLIN has developed proprietary algorithms that will reject several types of artifacts and still obtain an accurate measurement. In some instances, the artifact may become quite severe and the monitor will not be able to obtain an accurate blood pressure measurement. In this situation an alarm, when properly set, will notify the clinician of a change.

6.2 Pneumatic System

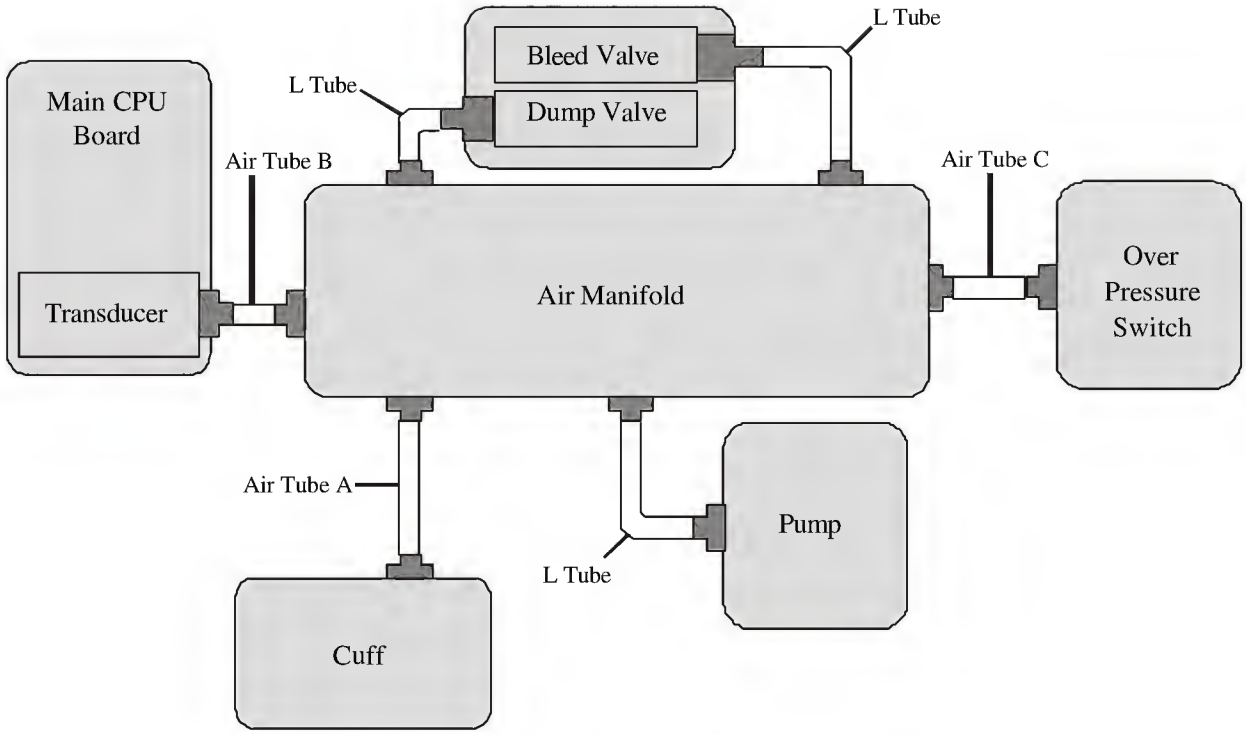


Figure 6.1 Press-Mate Pneumatic System

The Press-Mate determines blood pressure using the oscillometric method. Measurements are taken during cuff deflation, which is controlled by a micro-computer. Cuff pressure is deflated at a rate of 3 to 5 mmHg per second or per heart beat during blood pressure measurement. Rapid cuff deflation occurs under the following circumstances:

- When measurement is completed.
- When measurement is interrupted by pressing the START/STOP switch.
- When cuff pressure exceeds 325 mmHg.

The following sequence of events occurs when the pump is turned on by pressing the START/STOP switch on the front panel:

1. Air is immediately dispensed throughout the entire pneumatic system (Figure 6.1).

2. Once the pneumatic system is pressurized to 180 mmHg (120 mmHg in the neonatal mode), the pressure transducer on the main CPU board cuts power to the pump.

3. Air is then passed through he bleed valve so that the cuff pressure is decreased in a linear fashion and exhausted back through the pump.

4. The pressure transducer on the main CPU board then detects any oscillations from the cuff during deflation and converts them to digital code for the CPU to determine the systolic, diastolic and pulse rate readings.

5. Rapid, complete cuff deflation occurs after all readings have been recorded. The mechanical safety pressure switch automatically deflates the system if the pressure exceeds approximately 400 mmHg while the cuff is being inflated.

NOTE: Refer to Section 10 for schematics related to the functions described in this section.

6.3 Main PCB

The main Control Printed Circuit Board (PCB) of the Press-mate has many functions. Some of its circuits include:

Main and Sub CPUs
Cuff Pressure and Oscillation Inputs
Pump and Deflation Valve Controls
Front Panel Interface
Printer Control
Power Supply Control
RS232 Interface

The heart of the Main PCB is an eight-bit CPU (U12). The Main CPU controls the system according to the written program for the system, found on EPROM (Electrically Programmable Read-Only Memory) U13. Clock signals used for the timing of the Main CPU are provided by Crystal X1. The Main CPU works in conjunction with two, four-bit Sub CPUs. The first Sub CPU (U14) controls the Pump, Bleed Valve, and Dump Valve. The Sub CPU uses the pressure and the cuff oscillations from the pressure input circuit to control the rate of deflation of the pressure in the cuff circuit. The second Sub CPU (U15) controls the printer, while collecting information about battery power from the Battery Low/Empty Comparator Circuit (consisting mainly of OP3).

Cuff pressure is applied to the pressure transducer (PSI). This pressure creates a differential voltage imbalance across the arms of the transducer impedance bridge. This differential voltage is then amplified, filtered, and separated into a pressure signal, an adult oscillation signal, and a neonatal oscillation signal This separation is completed through the use of the CIC1 chip. The reason the signal is separated is because of the need to amplify the neonatal oscillation signal to a higher degree than the adult oscillation signal. The MUX chip (U13) then combines the pressure signal with either the adult oscillation signal or the neonatal oscillation signal upon the direction of the Main CPU. The combined signal (pressure signal with oscillations signal) is then sent to the 12-bit Analog-to Digital Converter (U30). U30 then translates this signal into a digital format for its transmission to U12 and U14. The Main CPU (U12) with the use of COLIN's proprietary algorithms, determines systolic, mean, diastolic, and pulse rate values. Once the Main CPU has determined these values, this information is then loaded in the RAM (U10) for switching by the I/O controller (U23) display board via connector (CN1).

Safety circuits like those found in U24, U17, and U3 watch for cuff over pressure as well as excessive cuff inflation/deflation duration conditions.

The Main PCB is connected to other major components in the Press-Mate via the following connectors:

CN1 - Connects the Main PCB with the Display Board
CN2 - Connects the Main PCB with the Power Supply
CN3 - Connects the Main PCB with the Pump and Valve Assemblies
CN4 - Connects the Main PCB with the Printer
CN6 - Main PCB RS232 Connection
CN10 - Connects the Main PCB to the Alarm Buzzer

6.4 Display PCB

The display PCB contains all LED displays; including twelve 7-segment LED displays, clock display, battery indicator LED, pulse level indicator LEDs, Start/Stop LED, Adult/Neonatal LEDs, and interval display. All front panel switches states are read by signal input controllers U1 and U2 and output to the Main PCB microprocessor via connector CN1. Data signal outputs are displayed on the LEDs and on the 2 character x 4-line LCD connected via CN2 to the display PCB.

6.5 Power Supply PCB

The power supply PCB regulates the AC power source supplied through connector CN101 to the secondary side of the transformer T1. Full wave rectification is provided by bridge rectifier D1. Relay RY1 completes the circuit through power oscillator IC4 to the secondary of transformer T2, where +12V and -12V are provided through the +12V regulator IC5 and -12V regulator IC6.

The +12V battery voltage is supplied through connector CN102. DC battery power is protected by three-amp fuse F1. Battery operation is selected when AC power is no longer detected at connector CN101. Relay RY1 opens and +12 volts is supplied by the battery.

6.6 Safety Functions for Overpressure

There are three safeguards for protection against excessive cuff pressure. When the pressure exceeds 325 mmHg (220 mmHg Neonatal), the software generates an error C19 and deflates the cuff. Pressure above 400 mmHg (240 mmHg neonatal) switches the pump off and causes an electrical hardware reset of the monitor. Pressures above 375 mmHg open a mechanical relief valve for rapid deflation. This information summarized in the table below.

Safety Function for Overpressure

Safety Function Activates When Cuff Pressure At:	Software	Electric Circuit	Mechanical Pressure Switch
ADULT	325	350 - 390	370 - 410
NEO	155	240 - 270	370 - 410
Safety Function Action:	Error "C19"	Stops Pumping --- Hardware Reset	Quick Deflation --- Turn off Power

6.7 Theory of Infrared Transmission, MS Series

The Sherwood IMS Genius communicates the results of a temperature measurement via an infrared communication link. The Genius contains an infrared transmission light-emitting diode (LED), which sends optical impulses to the Temp-Mate. A semi-conductor optical detector in the Temp-Mate receives the optical impulses and converts them to electrical impulses. Electronic circuitry within the Temp-Mate amplifies and conditions the electrical impulses, sending the resulting signal to the Press-Mate for storage and display.

A magnet in the Temp-Mate closes a reed switch in the Genius when the Genius is snapped into the Temp-Mate. When the reed switch in the Genius closes, the transmission of the temperature data is triggered. The optical impulses emanating from the Genius are in ASCII format. The structure of the transmitted message is as follows:

Preamble	Header	Data Frame	Data Frame	Data Frame	End

The three data frames contain identical data. If the Press-mate compares the contents of the three data frames and determines that they are not identical, the communicated data has an error and the Press-Mate will not accept the data. The message is transmitted at 4800 BAUD and each byte of the message has:

1 - Start Bit
8 - Data Bits
Even Parity
1 - Stop Bit

Upon receiving the optical data from the Genius, the Temp-Mate verifies that a valid, but not necessarily error-free, transmission has occurred. If the transmission is valid, the light on the Temp-Mate flashes. After the optical detector in the Temp-Mate has converted the optical signal into an electrical signal, other circuitry within the Temp-Mate make it RS232C compatible and pass it on to the Press-Mate.

The Press-Mate receives the signal and determines, from its structure, that the message came from a Genius thermometer. It verifies that the three data packets are identical and, if they are, displays and stores the temperature information. If the three data packets are not identical, the Genius must be removed from the Temp-Mate and replaced in the Temp-Mate so that the message is re-transmitted. When a valid, error-free message is received by the Press-Mate, the temperature is decoded and displayed on the LED display on the LCD and, if the printer is ON, recorded by the printer.

6.8 Theory of Operation: Genius Model 8300

Genius is an infrared sensing device adapted for use as a clinical thermometer. It senses the infrared emissions from the tympanic membrane and calculates body temperature as a function of infrared intensity. By adding a selectable linear offset to the calculation, Genius is able to display body temperature equivalent to an "Oral" or "Rectal" glass mercury thermometer, or Swan-Ganz catheter in the bloodstream. Genius also functions as a surface scanner. In this mode, it senses surface temperature variations.

6.9 How the Genius Derives the Temperature of an Infrared Target

1. Genius uses an infrared sensing device called a "thermopile detector" to measure infrared emissions from a target such as the tympanic membrane in the ear.

2. The thermopile is best described as a series of thermocouples, arranged around a blackened, "heat collecting" surface. The thermopile operates by outputting a voltage level, which is a function of the difference in temperature between the thermocouple "cold junctions" and the hot or "sensing junctions."

3. When the thermopile is pointed at a radiating target, energy strikes the blackened area inside the detector, causing a temperature differential between the sensing area and the cold junctions.

4. If we know the sensitivity of the thermopile, in terms of change of voltage output per degree of differential temperature (t. sensing junc. - t. cold junc.), and the temperature of the cold junction is known, then a formula can be derived to calculate target temperature.

6.10 Equivalence

If a patient's temperature were measured at four sites simultaneously: oral, rectal, arterial, and an infrared reading of the ear canal, you would get four separate but correlated readings.

There are two reasons an infrared reading in the ear canal is lower than core (arterial) temperature:

1. The ear is not a perfect "black body". In a perfect "black body", one hundred percent of the energy from a radiating object is emitted. In the ear canal, this is not so.

2. There is some heat loss down the ear canal due to thermal gradients.

By adding linear corrections, Genius is able to compensate for the two conditions described above. These linear corrections were based on extensive, non-biased, clinical study. By calibrating these corrections to ambient temperature, the problem described in condition 2 is minimized.

6.11 Pre-Scan Buffer

Because the probe tip of the Genius is not heated as in the First Temp Model 2000A, a new factor presents itself. Since heat energy will always travel from a warmer object to a colder object, the cold probe tip will act as a "heat-sink" to the ear canal, thus lowering the temperature in the outer portions of the ear canal. When the Genius probe is inserted into the ear, the infrared detector sees a peak temperature in a matter of milliseconds. Then, the peak rapidly drops off because of the heat-sinking effect of the cold probe. We call this "draw-down." Normally, this effect of draw-down would make it very difficult to get an accurate infrared reading of the ear canal without missing the peak.

However, this condition is remedied by use of a unique "Look-Ahead" feature in the Genius software:

1. When the user installs a disposable probe cover on the Genius probe tip, if the unit is set to "TYMPANIC" mode, it will immediately start to scan for a peak temperature, before the probe is actually inserted into the ear canal.

2. It keeps approximately one second's worth of temperature scans stored in a buffer. This buffer is continually refreshed. Because only the most recent second of data is held in the buffer, it is very unlikely that the unit would store a "false peak," such as would be seen when passing the probe tip over a hot cup of coffee.

3. When the probe is positioned in the ear canal, and the scan button is pressed, the Genius collects another buffer of data in addition to the "pre-scan buffer."

4. When determining target temperature, both buffers of data are examined for peak reading.

6.12 Sleep Mode Compared to, or Versus, Wake Mode

The Genius is able to conserve battery life by automatically placing itself into a special low-power ("sleep") mode, whenever it is left unused for approximately one minute.

1. When in sleep mode, the +5 volt supply is disconnected from all circuitry except the CPU.

2. Installing a Probe Cover will trigger an interrupt to the CPU, putting the CPU into its normal operation ("wake") mode.

3. After "wake-up," the CPU will cause the +5 volts to become active to the rest of the circuit board. A short time after the user completes the task of taking a temperature, the CPU will again return to sleep mode in order to conserve power.

6.13 Sleep/Wake-Up

1. Pin 29 of the CPU is INTO. INTO is used in this application to wake-up the CPU from low-power sleep mode.

2. When the unit is residing in its base, the reed switch, SW1, is open and INTO is pulled low. If the unit has not been used for at least one minute, the CPU is in its low-power sleep mode.

3. Removing the unit from the base causes the spring-loaded release button to drop to the "down" position. There is a magnet bonded to the underside of the blue RELEASE button.

4. The magnet causes the contact of SW1 to close. This causes a high on INTO.

5. When a probe cover is installed, the RELEASE button is forced high, causing the contacts of SW1 to open, thus causing a high to low transition on INTO, bringing the unit out of sleep mode.

6. If the probe cover is left in place but a temperature has still not been taken, after approximately one minute, the CPU will again go into low-power sleep mode. In this case the INTO line is held high as described in step 5. If this condition occurs, the menu will return to "USE NEW COVER." To reactivate the unit, the Probe Cover must be RELEASED and reinstalled.

7. You will notice that the MODE button (SW3) is tied to INTO. The reason is as follows: If the user desires to use the MODE button to change modes, or switch between °C and °F, he or she has no way of knowing, nor cares, if the CPU is awake or asleep. In case the CPU is asleep, there needs to be a mechanism in place to wake it up and cause it to perform its desired function. This is accomplished by tying the MODE button to INTO.

6.14 Power Supply

In:	9 Volt Alkaline Battery, 650 mah
Out:	+5 Volts
Current Consumption:	Sleep Mode - Approximately 25 µA Wake Mode - Approximately 7.5 mA
Battery Life:	6 to 8 months (average 600 temps / month)

6.15 The +5 Volt Supply

1. U8, a three-terminal linear regulator is used to produce a stable +5 volt output from a 9 volt input.

2. The +5 volt output always supplies current to the CPU.

3. When in sleep (low-power) mode, the CPU holds the gate of Q1 high, thus shutting off the +5 volts from the rest of the circuitry.

4. When the CPU is caused to wake-up (INTO), it puts a "low" on the gate of Q1, allowing Q1 to conduct current to the rest of the circuitry.

6.16 The -5 Volt Supply

The circuit uses a DC-to-DC converter (U9), to produce a -5 volt output from a +5 volt input. CPU Reset.

1. A high-to-low transition of a specified duration is required at pin 76 of the CPU for a power-on reset.

2. The first instant the battery is installed, C6 is discharged, and pin 76 of the CPU, being connected to the negative side of C6, is allowed to go high.

3. As C6 charges, pin 76 of the CPU drops low. This high-to-low transition, caused the CPU to generate an internal "reset".

6.17 Liquid Crystal Display

The drive circuitry and power to the LCD is internal to the CPU. The drive "duty-cycle" and "frequency" is a function of the 32 khz crystal, X1.

6.18 EEPROM

1. The Genius uses a 93CS46 EEPROM, which contains special internal data protection logic to minimize the possibility of data loss.

2. The Genius calibration table is contained in EEPROM memory (U2).

3. US is powered directly by one of the "high current" I/O pins on the CPU and is normally off.

4. When the CPU desires to read or write the EEPROM, it raises the I/O, supplying current to the EEPROM, then lowers it when the task is complete.

6.19 Analog to Digital Interface

1. U3, an "analog processor" is used to provide the analog to digital interface between the various sensors and the CPU.

2. The analog processor is being operated at a 14-bit (plus sign) resolution and samples at anywhere between 30 to 50 conversions per second (depending on amplitude of input).

6.20 Theory of Operation: FILAC

MCU Introduction

The heart of the F-2000 thermometer is a Motorola 8-bit microcontroller unit (MCU). This HCMOS single-chip MCU contains a CPU, clock oscillator, 7744 bytes of PROM, 176 bytes of RAM, 24 bidirectional I/O lines, a 16-bit timer, serial communications interface (SCI), and a serial peripheral interface (SPI).

A 2 mhz crystal oscillator connected between pins 42 and 43 provides the required clock frequency for the MCU.

6.21 Power On Reset

The MC34064P-5 Under Voltage Sensing Circuit (Q11) provides a reliable reset signal for the MCU by holding the reset line low until the power supply reaches 4.61 vdc. The time delay capacitor, C7, provides an additional 150 ms (approximately) delay to insure that the power supply is fully stabilized before the MCU comes out of reset. Q11 also causes the reset line to switch cleanly to ground when the power supply voltage drops to 4.59 vdc.

6.22 Front End Switch

In order to reduce current consumption and increase battery life, the F-2000 leaves the front-end circuitry off except when it is time to take a reading. The "switch" that controls this is Q1. When the MCU needs to take a reading, it biases Q1, bringing the front-end ground to true ground and applying power to U1, U2, and their associated components. When the reading is complete, Q1 is "turned off" by the MCU. If Q1 becomes shorted, excessive current draw will reduce the battery life. If Q1 becomes open, the F-2000 will display the "bAd CAL" message since it will not be able to complete the self-calibration checks with the front-end off.

6.23 Signal Conditioning

The F-2000 probe contains a thermistor, which provides the input to a differential amplifier (U1). The circuit is calibrated by VR1 to provide a 100 mv output when a resistance of 8343 ohms is applied to the probe input (see Section 7 - Calibration). This value represents 85.0°F, the low end of the F-2000's temperature scale.

6.24 Analog to Digital Conversion

The analog-to-digital converter (U2) is an eight-bit, four-channel serial device. The MCU provides the clock (CLK) and chip select signals (CS), then uses the same bi-directional port bit (PCO) to clock out a/d converter output (DO).

VREF is set by VR2 to the same value as the output of U1 when a resistance of 4746 ohms is applied to the probe input (see Section 7 - Calibration). This resistance represents 110.0°F, the high end of the F-2000's temperature scale. This adjustment ensures that the thermometer can read values over its entire range.

The following are a/d converter channel assignments:

Channel O — Reads the conditioned probe input value from the output of U1. The analog value read here is converted to a digital signal that the MCU uses to compute the values for the temperature display.

Channel 1 — Reads the 2.5-volt reference diode (D1). The value input here is used in the 5-volt power supply evaluation (see next paragraph).

Channel 2 — Reads the 5-volt power supply through a voltage divider consisting of two 47.5 K ohm resistors (R8, R12). The resulting value (nominally 2.5 volts) is compared to the value read from the 2.5-volt reference diode on channel 1. If the 5-volt supply has fallen out of regulation and the value read on this channel is significantly less than 2.5 volts, the F-2000 displays the "Lo bAt" message. An erroneous "Lo bAt" message could result if either the voltage divider components or D1 is defective.

Channel 3 — Reads the probe bridge before the signal is conditioned by U1. This is necessary to monitor probe values outside of the 85.0° to 110.0°F range. This input will detect shorted probe (<approximately 2.2K ohms) and open probe (>approximately 18K ohms) conditions.

6.25 Calibration Self-Check Circuitry

The F-2000 performs a two-point calibration self-check every time it is turned on. This is accomplished under a microcontroller program control by biasing the FET switches Q9 and Q10 in turn, switching precision calibration resistances into the F-2000 front-end circuitry. Q10 switches in the "Low Cal" resistance value represents 89.5°F (31.9°C). Q9 switches in the "Hi Cal" resistance value represent 104.9°F, (40.5°C). If actual readings vary more than 0.2°F (0.1°C), the F-2000 will flash the "bAd CAL" message until the problem is corrected. When the calibration check is completed, the thermistor is switched into the front-end circuitry via Q8 for normal operation.

If any of the calibration check components (Q9, Q10, R10, R11) fail, an erroneous "bAd CAL" message will be displayed. A failure in this area can be confirmed if a factory style calibration can be successfully performed (see Section 7). If the "bAd CAL" message persists, check the calibration circuitry for defective FETS, or calibration resistors out of tolerance.

If a "bAd Prb" message is displayed when a known good probe is connected to the F-2000, Q8 could be faulty.

6.26 Other Inputs

Switches S3-1 (at U2, PD4), S3-2 (at U3, PD3), S3-3 (at U3, PD5), and S2 (at U3, PD2), are used to select the pulse timer duration, Fahrenheit or Centigrade mode, calibration mode, and the direct or normal mode respectively. S3-1, S3-2 and S3-3 are located on the dip switch accessible through the battery compartment. S2 is a slide switch located on the back panel of the F-2000.

The pulse switch (at U3, PD1) is the momentary action membrane switch located on top of the F-2000 display and has a dual function. When in the direct or predict mode, pressing this button will initiate the pulse timing function. The F-2000 will display the letter "t" in the most significant digit of the display for the duration of time set by S3-1 above. When in the calibration mode, pressing this button toggles the low calibration and high calibration values into the display to visually verify and/or assist in the calibration of the F-2000.

6.27 Seven Segment Display and Audio Alarm

Port B (PB0-PB7) of the MCU is used to control each of four seven-segment displays. Individual seven-segment displays are multiplexed and controlled by pins PA0-PA3. Each digit is turned on in succession every four msec.

Pin 25 (PC6) of the MCU is an output line that controls the beeper used to signal that the final temperature is being displayed. The alarm may optionally be silenced by switching S3-4.

7.0 Calibration Verification for Press-Mate, Genius, and FILAC

Although the Press-Mate Model 8800 series of monitors have been factory calibrated for all of the test modes by the manufacturer, it is advisable that users verify the calibrations of these various test modes prior to using the monitor to ensure optimum performance.

7.1 Beginning Procedure: Press-Mate

To verify calibrations in the various test modes, you must first access the built-in test menu by executing the following sequence of events, thereby initiating and completing the self-test procedure. Some tests do require a calibrated manometer, a dummy cuff, and/or a rubber inflation bulb. To gain access to the menu:

1. Ensure the monitor is plugged into the AC power source.

2. Push the "ON" button on the front panel to activate the unit. If the battery is discharged, connect the unit to the AC outlet.

3. Set systolic "HI" alarm limit to 240 mmHg and "LO" alarm limit to 160 mmHg. (See Section 4.5 Alarm Settings for more information on how to set the alarm limits)

4. Turn the unit off by pressing the "OFF" button on the front panel.

5. Depress and hold the "START/STOP" button while simultaneously pressing the "ON" button. Do not release the "START/STOP" switch until the self-test procedure is completed, which will be indicated in the LCD window.

When the self-test procedure is complete, the unit will automatically enter the verification test mode. Each test will be displayed on the LCD while its test number is represented by each time interval displayed on the INTERVAL LEDs. With the use of the Interval up "Δ" and down "∇", select the test you would like to begin, Then press the "START/STOP" switch to begin the test. As each test is completed, progress through the menu to subsequent tests by pressing the INTERVAL up "Δ"and down "∇" switches.

NOTE: If adjustments are needed to bring the test values into calibration, contact COLIN'S Technical Services Department for assistance.

NOTE: Verification procedures in some test modes require the concurrent use of a calibrated manometer and a pressure-bulb hand pump along with a 700 cc or 220 cc dummy cuff, and Data Interface test connector. These items, except for the calibrated manometer, are included in COLIN MEDICAL INSTRUMENTS' Calibration Test Kit (part # C0690003A)

7.2 Test Menu

Interval	Test Name	Description
OFF	Alarm buzzer ON/OFF, CONT, TIME ADJUST, INITIAL INFLATION ADJUST	Alarm buzzer ON/OFF, Continued, Adjust Time, Date and Initial Inflation Controls all Smart Features if Applicable
CON	Safety Timer Test	Tests the "Watch Dog Timer Circuit"
1*	Telemeter Checker Mode	N/A
2*	TRM Test	N/A
2.5	Rear Panel SW Test, DIP Switch Indicator, Front Panel Button Test **-Recommended for PM Verification-**	Tests all rear panel switches (Adult/Neonatal, Display, Printer), Front Panel Buttons (except ON/OFF), Shows position of internal DIP switches
3	Air Leakage Test **-Recommended for PM Verification-**	Tests air leakage rate within the system
5	VER#, All Ram Clear	Verifies software version number. Clears all settings stored in RAM (including the systolic alarm settings).
10*	Telemeter Channel Test	N/A
15	Pump-Up Test	Automatically inflates the connected dummy cuff and calculates the rate of inflation
20	RS232C Test	VerifiesTransmitt and Receive lines of the RS232
30	Printer Test	Commands the printer to print out a test pattern
45	Initial Deflation Test **-Recommended for PM Verification-**	Automatically inflates and tests the deflation parameters of the monitor (Counts, Maxpress)
60	Deflation Test	Automatically inflates the connected dummy cuff can, the static deflation rate is measured and then displayed
120	VER#, Display Test **-Recommended for PM Verification-**	Verifies software version number. Tests all elements of front panel display
180	Static Calibration Test **-Recommended for PM Verification-**	Allows user to verify the accuracy of the internal pressure sensor, and Overpressure settings
180_____	Software Overpressure Test Systolic high alarm setting 240 Systolic low alarm setting 150	Allows user to verify the accuracy of the software Overpressure setting.

* These tests can only be completed on Press-Mates with the telemetry option.

7.3 Testing Sequence

The manufacturer recommends that the user carry out the test sequence in the order presented in the following subparagraphs, although skipping to a specific test is possible. For the interval order, the tests are found in, see Section 7.2.

All test items correspond to the time intervals displayed in the "INTERVAL" window as follows:

OFF Alarm Buzzer ON/OFF, Time Adjust and Interval, all Smart Features if applicable Follow the directions given in the Operation Manual.

CON Safety Timer Test.

NOTE: The CON Safety Timer Test is a built-in safety precaution that activates when one or both of the following conditions are met:
- **Pump is on for approximately 140 seconds. (The acceptable range is 120 to 160 seconds)**
- **Dump valve remains closed for 140 seconds while the unit is in use.**
- **Repeat Steps 4 and 5 of beginning of test procedure when test is complete.**

The cuff connector should be open.

a. Safety Timer Check No. 1 (only pump on)
Press the START/STOP switch to show "-1-" in SYSTOLIC window. Press the START/STOP switch again to start test. While the pump is being operated, "-1-" flashes and elapsed time (in seconds) is displayed in the PULSE window (DIASTOLIC window for model 8800 Press-Mates). After about 120 seconds, the safety timer turns the power OFF and the dump valve is opened.

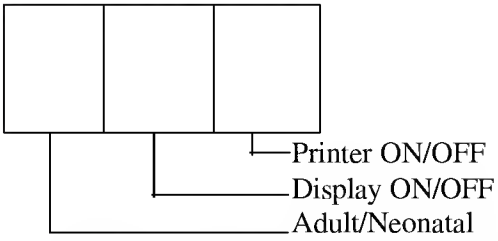
b. Safety Timer Check No. 2 (only dump close)
Press the START/STOP switch and the LIST UP and DOWN switch to show "-2-" on SYSTOLIC indicator. Press the START/STOP switch again to start the test. The timer stops operating about 140 seconds after closing the dump valve. While the dump valve is being closed, "-2-" flashes and elapsed time (in seconds) is displayed in the PULSE window (DIASTOLIC window for model 8800 Press-Mates). After about 140 seconds, the safety timer turns the power OFF and the dump valve is opened.

c. Safety Time Check No. 3 (dump and bleed close)
Press the START/STOP switch and the LIST UP and DOWN switch to show "-3-" on the SYSTOLIC indicator. Press the START/STOP switch again to start the test. The timer stops operating about 140 seconds after closing the dump and bleed valves. While the dump and bleed valves are closed, "-3-" flashes and elapsed time (in seconds) is shown in the PULSE window (DIASTOLIC window for model 8800 Press-Mates). After about 140 seconds, the safety timer turns the power OFF and the dump valve is opened.

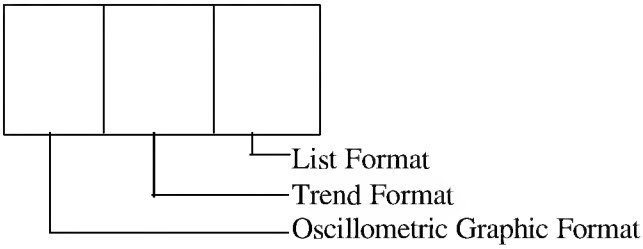
2.5 Rear Panel Switch Test

Push the START/STOP switch to start the test. Each LED digit will show the rear panel switch settings as follows ("0" = OFF; "1" = ON).

The display of the rear switch settings can be found on the DIASTOLIC window of the model 8800MS and the MEAN window of all other Press-Mate models. Example as shown:



The display of the settings of the Print Mode switch (if applicable) will be displayed in the PULSE window of the model 8800MS and the DIASTOLIC window of all other Press-Mate Models. Example as shown:



On the LCD display, the lower two lines show the condition of the eight internal DIP switches ("0" = OFF; "1" = ON). The top line of the LCD display reads out the last front panel sheet switch that was activated. Verify that all sheet switch changes correspond to the LCD description.

To exit this test, press the START/STOP switch and the INTERVAL UP switch simultaneously.

3 Air Leakage Test

a. Attach the 220 cc dummy cuff to the cuff connector as shows in Figure 7.1. Attach shorting block RS232.
b. Press the START/STOP switch to start the test. The dummy cuff will inflate to about 300mmHg.
c. The DIA indicator flashes with current pressure while the test is being conducted.
d. After one minute, the current pressure valve is displayed in the SYSTOLIC window. After one more minute, it will subtract the current pressure in the DIASTOLIC window (MEAN window for model 8800 Press-Mates) from the one in the SYSTOLIC window to come up with the leaked pressure, which will be displayed in the PULSE window (DIASTOLIC window for model 8800 Press-Mates).
e. The acceptable range for the leaked pressure is < 3 mmHg.
f. The air leakage test is complete when the cuff can is totally deflated.

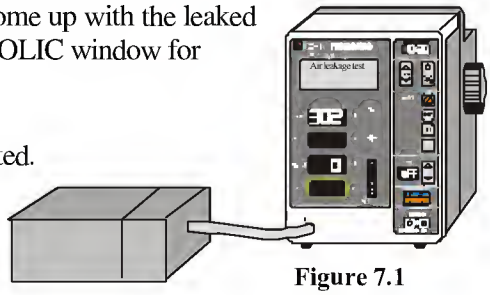


Figure 7.1 Press-Mate Model 8800 configuration for Air Leakage Test

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5 VER#, All RAM Clear Test

Use this test to verify the current software version number and clear the RAM contents. Remember that when the RAM is cleared, the previously set ALARM SYSTOLIC settings are also cleared. This means that after the "ALL RAM CLEAR" is done, the Press-Mate will return to the normal operating mode. Steps 3 through 5 in Section "A" at the beginning of this calibration section must be repeated.

15 Pump-Up (Inflation) Test

Normal Mode Pump up Test

a. Attach the 700 cc dummy cuff to the cuff connector (See Figure 7.1)
b. Push the START/STOP switch to start the test
c. The dummy cuff will inflate to about 250 mmHg, and the monitor will calculate the time of inflation.
d. During inflation, the current pressure is displayed in the SYSTOLIC, DIASTOLIC, and PULSE LED windows (SYSTOLIC, MEAN, and DIASTOLIC windows for model 8800 Press-Mates).
e. Once the test is complete, the time taken to inflate the 700 cc dummy cuff to 250 mmHg is displayed in the SYSTOLIC window in seconds, less the decimal point (e.g., 40 = 4.0 seconds).
f. The acceptable range is 2.8 to 7.3 seconds.

Auto-Up Mode (if applicable)

a. Press the list up to select "2 Auto Up Mode".
b. Repeat steps a-e of normal mode pump up test.
c. The acceptable range is 2.5 to 8.5 seconds.

20 RS232 Test

a. Connect the RS232 connector to the RS232 port on the back of the Press-Mate.
b. Press the START button. This initiates the transmission of a stream of data from the transmit line back into the receive line. The monitor will then verify the accuracy of this stream.
c. If the transmission was acceptable, "PAS" will be displayed in the PULSE window; if the transmission was not acceptable, "bAd" will be displayed in the PULSE window.

30 Printer Test

a. Push the START/STOP button to start the test.
b. The printer will respond by printing out the following patterns:
c. Inspect the print-out for quality.

45 Initial Deflation Test

In this test, the Press-Mate will inflate the 220 cc dummy cuff to about 180 mmHg, then slowly deflate the cuff while calculating the operating parameters as follows:

COUNTS — Time from the beginning of the deflation period to the point at which the cuff pressure is 25 mmHg below the initial inflated cuff pressure (180 mmHg).

MAXPRESS — Maximum deflation rate from the beginning of the deflation period to the point at which the cuff pressure is 40 mmHg below the initial inflated cuff pressure.

a. Connect the 220 cc dummy cuff to the cuff connector.
b. Press the START/STOP switch to start the test.
c. The 220 cc dummy cuff will inflate to 180 mmHg and then slowly deflate the cuff while calculating the operating parameters. The initial deflation parameters, COUNTS, and MAXPRESS are displayed in the SYSTOLIC and DIASTOLIC windows (MEAN window for model 8800 Press-Mates). The acceptable range is as follows:

COUNT	5 — 13
MAXPRESS	4 — 10

60 Deflation Test

a. Attach the 220 cc dummy cuff to the cuff connector (See Figure 7.2).
b. Press the START/STOP switch to start the test.
c. The 220 cc dummy cuff will inflate to about 300 mmHg, then slowly deflate while calculating the deflation rate.
d. When the test is complete, results will be displayed in the SYSTOLIC, DIASTOLIC, PULSE, and TEMP windows (SYSTOLIC, MEAN, DIASTOLIC, and PULSE windows in model 8800 Press-Mates) in mmHg/sec, less the decimal points (e.g., 40 = 4 mmHg/sec). Acceptable ranges are as follows:

Window 8800MS	Window 8800	Pressure Range	Time
SYSTOLIC	SYSTOLIC	260 to 180 mmHg	4.6 - 6.2 mmHg/sec
DIASTOLIC	MEAN	180 to 100 mmHg	4.6 - 6.2 mmHg/sec
PULSE	DIASTOLIC	100 to 60 mmHg	3.3 - 5.0 mmHg/sec
TEMP	PULSE	60 to 30 mmHg	2.6 - 4.4 mmHg/sec

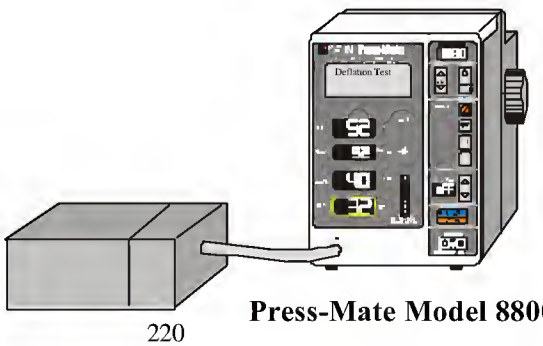

Figure 7.2

Press-Mate Model 8800 configuration for Deflation Testing

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120 Display Test

a. Push the START/STOP switch to start the test.
b. Half of all the display segments will operate. Push the START/STOP switch again to check the remaining display segments.
c. After completing this test, select another test by pushing the INTERVAL UP key.

180 Calibration Mode Test

(Use apparatus shown in Figure 7.3)

In this test, the user can verify the accuracy of the internal pressure sensor by introducing a known air pressure valve into the Press-Mate then comparing the pressure value from the display to that of the connected calibrated manometer.

a. Make sure that there is nothing connected to the cuff connector.
b. Press the START/STOP switch to start the test.
c. The unit will begin to pump air out of the cuff connector.
d. Use a finger to completely cover the cuff connector opening, then release. This will reset all displayed values to zero.
e. Connect a hand pump and a calibrated manometer to the cuff connector.
f. Use the hand pump to change the pressure within the system while comparing the values from the manometer to the display.
g. The input pressure and the tolerances are as follows:

Input Pressure	Acceptable Pressure
0 mmHg	0 mmHg
100 mmHg	100 ± 1 mmHg
150 mmHg	150 ± 2 mmHg
300 mmHg	300 ± 3 mmHg

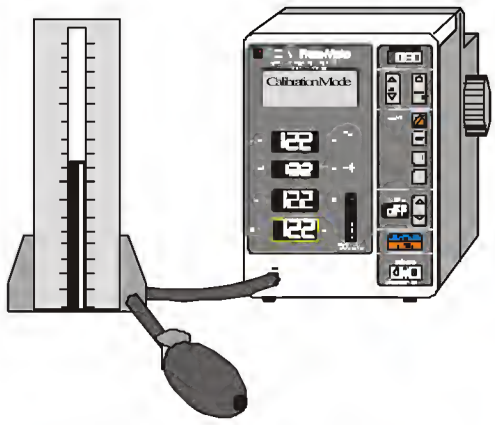

Figure 7.3

Press-Mate Model 8800 configuration for Calibration Test

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180 Electrical Circuit Overpressure Test

(Use apparatus shown in Figure 7.3)

a. Make sure that there is nothing connected to the cuff connector.
b. Press the START/STOP switch to start the test
c. The unit will begin to pump air out of the cuff connector.
d. Use a finger to completely cover the cuff connector opening, then release. This will reset all displayed values to zero.
e. Connect a hand pump and a calibrated manometer to the cuff connector.
f. Increase pressure in the circuit.
g. Acceptable limit: 350-390 mmHg.

NOTE: Monitor will automatically deflate at electrical circuit Overpressure point.

180 Mechanical Switch Overpressure Test

(Use apparatus shown in Figure 7.3)

In this test, the user can verify the limit of the mechanical switch Overpressure point. Place the unit in the Calibration Mode and complete the following:

a. Place the RS232 test connector on the RS232 port and increase the circuit pressure.
b. Make sure that there is nothing connected to the cuff connector.
c. Press the START/STOP switch to start the test.
d. The unit will begin to pump air out of the cuff connector.
e. Use a finger to completely cover the cuff connector opening, then release. This will reset all displayed values to zero.
f. Connect a hand pump and a calibrated manometer to the cuff connector.
g. Increase pressure to the circuit.
h. Acceptable limit: 370-410 mmHg

NOTE: Monitor will automatically deflate at mechanical switch Overpressure point and turn power off.

180 Software Overpressure Test

(Use apparatus shown in Figure 7.4)

a. Turn the power ON and wait for the "SELF TEST" to complete.
b. Set the systolic HI alarm limit to 240 and the LO alarm limit to 150.
c. Set the interval timer at 180 minutes.
d. Turn power OFF
e. Connect the monitor to test apparatus as shown in Figure 7.4.
f. Depress and hold the START/STOP switch while turning power on. Do not release the START/ STOP switch until the self-test is complete.
g. The unit will inflate to 180 mmHg. You have 15 seconds to increase the pressure by squeezing the rubber bulb. Once the Overpressure limit is reached, the unit resets itself and reinflates. "C19 Pressure Error" will appear on the LCD display.
h. Acceptable limit: 320-330 mmHg.

NOTE: If it takes longer than 15 seconds to increase the pressure, "C13 Motion Artifact" will be displayed on the LCD screen. When nearing the Overpressure point, increase the pressure as slowly as possible to get an accurate reading. Recommendation from COLIN, insert a large syringe into the tubing and then use the syringe for a gradual increase in pressure to help from spiking the pressure making it difficult to recognize the actual pressure upon Overpressure detection of the unit.

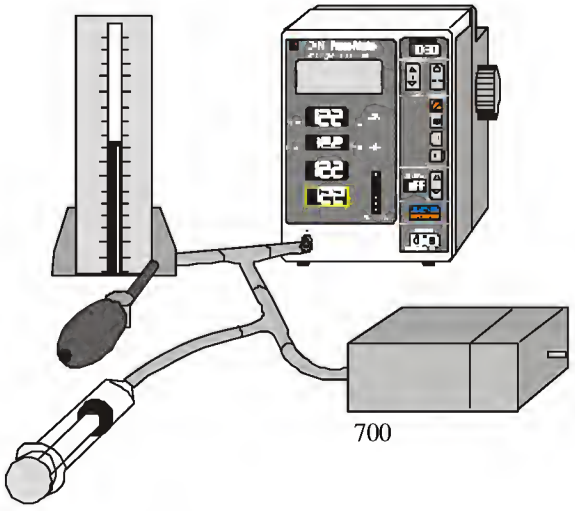

Figure 7.4

Press-Mate Model 8800 configuration for Software Overpressure Test

7.4 Calibration Verification: Genius

The Genius is constructed using solid-state electronics with surface-mount components for durability and reliability. The only moving part in the probe is the RELEASE button assembly, which provides for long service life. There are no electronic adjustments available to the biomedical engineer. All calibration is performed digitally and is stored in nonvolatile EEPROM.

7.5 Recommended Calibration Interval

The Genius is constructed with components selected for their extremely low long-term drift characteristics. Furthermore, two burn-in cycles during manufacture ensure that calibration drift will be minimal. However, all electronic components exhibit some degree of drift, over time. To ensure accuracy to specification, Sherwood I.M.S. recommends calibration of your Genius every 12 months.

7.6 User Calibration

Factory Calibration vs. User Calibration

The user is given the ability to check system calibration at two set-points (approximately 98°F and 102°F) and has the option of adjusting the calibration in the field, by the entry of a "constant offset" into the calibration memory. If the system calibration cannot be corrected to specification with this simple adjustment, it will have to be returned to the factory where the entire calibration curve will be checked and recalculated. In most cases, however, the simple "offset" adjustment in the field is all that is required to bring the system calibration back into American Society for Testing and Materials (A.S.T.M.) specifications.

7.7 Calibration Sources

Because the Genius is an "optical" thermometer, not a "contact" thermometer, it must be stressed that all conventional methods which would be used to check calibration on a "contact" thermometer do not apply and, in fact, could seriously damage this thermometer. The importance of using a proper "blackbody" radiator as the only type of calibration source cannot be over-emphasized. Furthermore, because of the unique shape of the head of the Genius probe, it is not possible to rely on some "commercial" infrared calibration devices, or devices provided for other infrared thermometers.

Acceptable Calibration Sources

1. Sherwood Medical Model 3000A-CL electronic calibrator.

2. Specially designed "blackbody adapter" (available through Sherwood Medical, ask for Part # 3000A-BB). This blackbody adapter is designed to be used with an electronically controlled water bath and NBS traceable probe. Instructions are shipped with the device.

Unacceptable Calibration Sources

1. Model 2000A-CL electronic calibrator: the shape of the calibration cavity is such that the Genius will not properly fit into the device.

2. An ear: because of "emissivity" and "draw-down" problems the ear is inappropriate to use as a calibration "device". (See Sections 6 for explanations of "emissivity" and "draw-down."

7.8 Using the 3000A-CL Electronic Calibrator

Since a complete calibrator Operation Manual is shipped with every 3000A-CL calibrator, the information it contains is not repeated here. However, before attempting to use a 3000A-CL calibrator, and, before attempting to adjust calibration offset, please read the instruction manual carefully. Pay careful attention to the special section at the end of the instructions, entitled: "Do's and Don't's of Using the 3000A-CL Electronic Calibrator."

7.9 Using a Blackbody in a Stirred Water Bath

Since the instructions for using the Sherwood Medical "blackbody" adapter are written as a separate document, contact Sherwood Medical at 800-535-5158 for more information.

7.10 Calibration Self-Check: FILAC

The F-2000 automatically performs a calibration check each time it is turned on by reading fixed precision calibration resistances built into the F-2000 circuitry and comparing the readings to programmed ideal values. This test is transparent to the user. If the test fails, the F-2000 will alert the user by continuously flashing a "bAd CAL" message.

If the calibration self-check fails, the F-2000 may be recalibrated using one of two methods. The factory calibration procedure is the more accurate of the two and requires the use of an accurate digital volt meter and resistor decade box. The field calibration procedures is much easier to perform and requires no special test equipment. Though the field calibration procedure is not quite as accurate as the factory calibration procedure, it will still yield results within the F-2000 specifications $\pm$ 0.2°F ($\pm$ 0°C).

7.11 Factory Recalibration Procedure

(Refer to PCB Schematic and Assembly Diagram)

Equipment Required: Digital Volt Meter, 1 mv Resolution
Resistor Decade Box
Mini Clip Leads

1. Remove the probe from the monitor.
2. Carefully remove the F-2000 case top, leaving the fascia and battery compartment in place.
3. Replace the battery compartment screw to hold the door closed during calibration.
4. Set the DIRECT?NORMAL switch to the "direct" position.
5. Connect resistor decade box to pins 2 and 3 of a J1. Set the decade box to 8343 ohms +/- 2 ohms.
6. Connect the DVM to T1-2 (-) and T1-7 (+).
7. On J1, the probe jack, jumper between pins 1 and 4 with a clip lead. Next, jumper between T1-2 and J1-4. Display will read approximately 85.0.

8. Adjust VR1 to obtain a reading of 100 mv, +/- 5 mv on the DVM.

9. Adjust the decade box to 4746 ohms, +/- 2 ohms. Record the voltage now observed on the DVM.

10. Connect the DVM + lead to T1-4.

11. Adjust VR2 until the DVM reading is the same as that recorded in Step 9 (+/- 10 mv)

12. Remove the jumper from J1 and disconnect test leads and jumper from T1.

13. The F-2000 calibration is complete. Reset the DIRECT/NORMAL switch to the normal position and reassemble the F-2000.

7.12 Field Recalibration Procedure

1. Carefully remove the F-2000 case top leaving the fascia and battery compartment in place.

2. Open the battery compartment door and switch S3-3 to the "CAL" position. Close the door and replace the battery compartment screw to hold the door closed during calibration.

3. Turn the F-2000 on. A value near the low calibration value of 89.5°F (31.9°C) should be displayed.

4. Adjust VR1 until the display reads 89.5°F (31.9°C).

5. Depress the pulse timer button. A value close to the high calibration value of 104.9°F (40.5°C) should be displayed.

6. Adjust VR2 until the display reads 104.9°F (40.5°C).

7. Successive presses of the pulse button will toggle the low calibration and high calibration values into the display.

NOTE: Calibration adjustments on one end of the range might throw off the other end. If you make an adjustment at the high end, check the low end to ensure you are still in calibration. If you make an adjustment on the low end, check the high end to ensure appropriate calibration.

8. Repeat these procedures, adjusting high end then low end, several times until you reach the desired readings on both ends.

9. The F-2000 calibration is complete. Return 53-3 to the normal position and reassemble the thermometer.

8.0 Troubleshooting

Caution: Repairs and calibration should be performed by qualified service personnel.

8.1 Troubleshooting Guide

When an error occurs during measurement, a message appears on the fourth line of the information within the LCD window. Explanations of these errors are listed in the following table.

Symptom	Check
Blood pressure unit will not turn on	Is battery light green (if not using A/C power)? If not, plug unit in for battery charging. Is the power cord properly inserted into a working electrical outlet? Is it completely plugged into A/C power outlet on rear of unit? Have a qualified service personnel verify the "slow blow fuses."
Blood pressure unit will not display	Is the "DISPLAY" switch on the rear panel in the "ON" position? Is the power cord properly inserted into an electrical outlet? (For measurements on battery power, check the battery indicator on the front of the unit is illuminated green.)
Cuff will not inflate	Are all cuff and cuff hose fittings secure and without leaks? Are error codes displayed on the LCD screen on the front of the unit? If so, call COLIN Technical Services at 800-829-8100. If the displayed cuff pressure is increasing rapidly but the cuff is still not inflating, check to see if the cuff hose is crimped or bent.
Printer will not print	Is the "PRINTER" switch on the rear of the unit in the "ON" position? Is the paper loaded properly? Are you using COLIN brand thermal paper?
Blood pressure measurement results are questionable	Are you using the correct size cuff and proper cuff wrapping technique? See cuff placement instructions in this manual.
Temperature measurement results are questionable	If measurements are still questionable, refer unit to Biomedical Engineering or COLIN Technical Services for a calibration verification test.

Note: Blood pressure measurements on patients with severe arrhythmia may be difficult using this instrument.

8.2 Troubleshooting – Possible Causes and Remedies

While monitoring blood pressure, problems may occur causing difficulty with accuracy, monitor performance and patient comfort.

The following information may be used to help troubleshoot some of these problems:

Patient comfort-

Patient comfort in most cases is compromised by not using the appropriate cuff for the patient, or using proper placement techniques. *Verify the cuff size, placement of the cuff over the brachial artery, placement of the cuff above 1.5 inches above the elbow, as well as how tight the cuff was wrapped.*

Patient movement or arrythmia may also cause the unit to take longer and cause additional discomfort for the patient. *Observe the patient to see if motion may have affected the monitor, or if the monitor has a printer, look at the printout to see if the motion artifact mark appeared (#).*

Monitor settings may also influence the comfort of the patient. Make sure the appropriate inflation settings have been used and that the monitor is in the appropriate adult or neonatal mode. A small leak in the cuff or air tube may also cause the unit to take longer to obtain a measurement. *Verify the inflation pressure settings of the monitor. Check the integrity of the cuff and hose by wrapping the cuff around a cylindrical object and placing the monitor into the service mode and running the calibration test, if the pressure does not remain at constant pressure, replace a component at a time (cuff, hose, monitor) until the leak has been ceased.*

Accuracy-

The accuracy of the monitor can only be judged by verifying the patient's blood pressure against another source. *This verification can only be done if second measurement occurs immediately after the first measurement has been taken. You can also verify the measurement by first validating the calibration of the monitors transducer, verify no leaks are present in the monitor, cuff, or hose, then place a stethoscope under the cuff and let a qualified person take an auscultatory measurement at the same time as the monitor. This auscultatory measurement will use the pressure from the monitor's display and the automatic deflation of the monitor as well. Remember an auscultatory measurement averages a 5-7 mmHg lower systolic and 5-7mmHg higher diastolic value than an oscillometric measurement.*

Monitor failures-

Colin monitors offer the user a source of displayed information to help them with monitor failures. These messages include advisory, caution, and error codes. The following information may be displayed.

Messages-

- Battery Low and Charge Battery- These messages alert the user that the monitor is operating on battery power and must be plugged into an AC source for continued operation. *If one of these messages appear and the monitor is connected to an AC source, verify the power cord, fuses, and if AC is even at the plug itself.*

- Blank Mode- This message alerts the user that the display switch on the back of the monitor is in the OFF position.

- E01 and E02 RAM/ROM Failure- These messages alert the user to failure of the self test of the unit. *If one of these messages appear, restart the unit and if the message reappears the unit must be serviced by the appropriate personnel.*

- E03 Cuff Disconnect- Is displayed when the monitor did not inflate to a pressure above 10 mmHg within 10 seconds. *Verify cuff and hose for extreme air leakage. Also verify that the connections of the above to the monitor or cuff are made and tight. If the pump did not even start, the monitor requires repair.*

- C11 Check Cuff- Is displayed when the monitor did not inflate to the inflation pressure setting within 30 seconds. *Verify for a small leak in the monitor, cuff, hose, or connection.*

- C12 Check Cuff- The cuff deflated to a pressure of 10 mmHg, and no measurement was z *that a neonatal cuff is not being used in the adult mode.*

8.3 Error Codes — Blood Pressure Monitor

Error Code	Displayed Message	Description	Probable Cause
E01	"E01 Internal Error"	RAM failure	
E02	"E02 Internal Error"	ROM failure	
E03	"E03 Cuff Disconnect"	The pressure was less than 10 mmHg more than 10 seconds after starting the pump.	Check connection between the unit and air hose, and cuff.
E21	"E21 Internal Error"		Shorting block on back of unit.
C11	"C11 Check Cuff"	The cuff pressure did not reach the specified value within 30 seconds (10 seconds for neonates) after starting measurement.	Check the cuff and hose connector for air leaks.
C12	"C12 Check Cuff"	The pressure dropped to 10 mmHg but the measurement was not completed.	Check the cuff for normal position and patient motion.
C13	"C13 Motion Artifact"	The air was not discharged within 15 seconds because of body movement.	Check body movement or arrhythmic patient.
C14	"C14 Reinflation"	Apply pressure again.	Check insufficient pressure because of high blood pressure.
C15	"C15 Irregular Pulse"	Abnormal oscillometric waveform.	Check body movement or arrhythmic patient.
C16	"C16 Weak Pulse"	Impossible to measure due to noise by arrythmia or body movement.	See C15
C17	"C17 Time-Out"	Measurement took more than 90 seconds.	Check for cause of obstructed air discharge, e.g., movement of patient or bent or crimped hose.
C18	"C18 Time-Out"	More than 100 pulses were detected during measurement.	See C17
C19	"C19 Pressure Error"	Cuff pressure rose above 325 mmHg (150 mmHg for neonates) during measurement.	Check for folded patient arm or bent hose.
C20	"C20 Low Pulse Error"	Pulse was too low to measure.	Check proper attachment of cuff.

8.4 Problems with the unit – Cause & Solution

As problems occur with the operation of the unit, you can use the following possible solutions to aid in the troubleshooting of the problem. You may be required to utilize this information in conjunction with the service calibration procedures to accurately troubleshoot the source of the problem.

Cannot turn ON the power to the unit.	
CAUSE	SOLUTION
Cord is unplugged or loose	Check the power input cord connections and or verify with a known good power cord.
Fuses on back panel defective	Verify that the fuses are not defective and if so, please replace the defective fuses with the appropriate sizes as marked on the back panel of the monitor. (Slow blow type only)
Sheet Switch Defective	Verify that the ON and OFF buttons are not stuck, and that you can feel the depression of the dome as each button is pressed.
Transformer may be defective	Verify the voltages at the output of the transformer
Power supply defective	Verify the output voltages of the power supply, also check pin 6 to pin 8 of the power supply as the front switch ON is de pressed the signal should be pulled low.
Main board defective	If pin 6 is not pulled low as the ON switch is depressed and pin 31 of CN1 is pulled low. Then replace the main board.

The unit overheats	
CAUSE	SOLUTION
The unit is too close to its surroundings	Remove objects that are too close to the bottom of the unit.
The battery is defective	Replace defective battery. If battery draws too much current overheating may occur.

The unit will not operate on battery power.	
CAUSE	SOLUTION
Defective battery connection	Remove and battery door and clean and check connections.
The battery is defective	Replace defective battery.
Blown F1 fuse on Power supply	Replace defective 3A fuse.

The unit seems to turn ON but the display is blank or fully lit.	
CAUSE	SOLUTION
Display switch is OFF	Verify the display switch on the rear case is on.
LCD ribbon cable dislodged	Verify the ribbon cable is correctly attached.
VR1 on main board changed	Verify VR1 on the main board is appropriately set.
LCD defective	Rework or Replace defective LCD. If the NEO LED lights, but the unit will not function, this indicates a defective LCD.
Main Board defective	Replace defective main board.
Display board may be defective	Replace Display board
EPROM defective	If the unit's software was just upgraded, the EPROMs may be inserted incorrectly or is defective.

Unit will not turn off	
CAUSE	SOLUTION
Sheet switch failure	Verify that as the OFF switch is depressed a bubble or depression can be felt. Replace sheet switch if no depression is found.
Power supply is defective	If the OFF switch is depressed, pin 6 should be pulled high. If it is replace RY1 or the power supply.
Main board is defective	If pin 6 was no pulled high then replace the defective main board.

No sound	
CAUSE	SOLUTION
Alarm Mute Active	Verify in the configuration screen that Volume is ON
Speaker wire disconnected	Verify connection of Speaker wire
Speaker is defective	Verify if power is passing through to speaker, if so replace defective speaker

Front panel switches don't work or LEDs will not light	
CAUSE	SOLUTION
Sheet switch is defective Or not connected	Verify the ribbon connector from the switch to the display board is connected. If you cannot feel the depression of the switch, replace the sheet switch.
Main Board Failure	Replace Main board
Display Board is defective	Replace display board or LED is found to have missing segments or do not light.

Time clock is drifting or cannot set time	
CAUSE	SOLUTION
Time is not set	Reset time selection and try again
Clock Battery defective	Replace clock battery, verify that when unit is ON, 2.4 Vdc charger voltage is present.
Clock IC defective	Replace U2 clock IC
Main board is defective	Replace defective main board.

Unreliable readings (Inaccurate NIBP)	
CAUSE	SOLUTION
Rapid cuff deflation	Check for leaks in hose and cuff.
Cuff Placement and Positioning	Verify appropriate cuff placement and positioning
Cuff not at Heart Level	Verify and place cuff at patient's heart level
Patient movement	Calibrate TBP measurement by initiating a cuff calibration.
Position Indicators	Check and adjust placement of sensor
Severe patient arrhythmia	Verify with a manual cuff measurement
Vibrations including shivering	Look for patient movement, take appropriate measures

Unreliable readings (Inaccurate NIBP) Continued	
CAUSE	SOLUTION
Unstable blood pressure	Verify patient for reciprocal pulsations or respiratory alterations.
Patient Physiology	Patient's pulse pressure may not be adequate for monitor to allow TBP measurements. Continue with oscillometric measurements.
Calibration (NIBP)	Check the calibration of the NIBP transducer
Deflation Speed	Check for internal leaks and deflation speed.

Cuff does not inflate	
CAUSE	SOLUTION
Cuff hose may have a faulty connection	Check all connections and hoses for damage
Cuff may have a leak	Check connections and replace is faulty
Sheet switch is defective	Verify depression of Start/Stop button. Replace defective sheet switch.
Power supply failure	Verify output voltages, repair or replace power supply.
Pump failure	Verify that when 12 Vdc is applied to pump, pump starts
Main Board failure	Verify that when Start/Stop switch is depressed, 12 Vdc is applied between pins 1 and 2 of CN3. Replace defective Main board.

Overall Battery Life is suspect	
CAUSE	SOLUTION
Battery charge rate low	Verify charge voltage to the battery is from 14.2-14.8 Vdc.
The battery is defective	Replace defective battery. You can test the battery by completing the following steps: 1. Test the battery with a battery analyzer. 2. Verify that once charged the battery voltage remains above 12 Volts and does not continue to fall. 3. Place the unit into the Safety timer test, run the test three times, each time verify the battery voltage stays above 12 volts.

Overall Battery Life is suspect	
CAUSE	SOLUTION
Blown F1 fuse on Power supply	Replace defective 3A fuse.
Low/Empty Indicator failure	Connect a DC power supply to the unit in place of the battery. Slowly decrease the voltage of the power supply from 14.0 volts until the "Battery Low" indicator is shown. The voltage should be 11.8 +/- .1 volts. The "Battery Empty" indicator will appear at 11.2 +/- .1 volts. Replace main board or rework circuit as required.
Use/Charging Style	If the unit is not connected to AC the required time throughout the day compared to the time in use, the battery may prematurely fail due to inadequate charging. Replace battery and change charging circuit as described in procedure
Power Source	Verify appropriate AC power from plug, to cord, to fuses, to transformer, to power supply.

8.5 Repair Notes

While repairs are in progress it is always important not only to verify operation after the repair, but to also check for the following, if you are to familiar with one of the below mentioned upgrades or kits, call Colin's Technical Service at 800-829-6427:

Front Case- When replacing the front case make sure to check the following:

1. Chassis is not bent or damaged.
2. Nylon washers between LCD and front case are present.
3. No nicks or holes are in LCD interface cable.
4. Grounding strap of sheet switch is connected appropriately.

Rear Case- When replacing the rear case make sure to check the following:

1. Has the main AC ON/OFF switch been removed with the upgrade?
2. Is the metal C-clamp for the pole holder bracket straight and not opened beyond its normal C shape. Use of a ball peen hammer or vise will help to return bracket to its normal shape.
3. Is the rubber pole holder still in place on the plastic pole mount?
4. Is the grounding bracket placed onto the new rear case (bracket is located next to the battery housing and connects with a bronze 3 x 4 to the rear case).
5. Has the unit been upgraded with the top left and right reinforcement bracket kits, they are placed onto the chassis and extend to protect the top corners of the rear case?
6. Has the unit's pole holder been upgraded with the metal sliding bracket and the white pole sliders ears been removed.
7. Verify the battery connector is again attached as the rear case is placed back onto the unit.
8. Verify the battery felt is not between the rear and front case joint.

Battery- When the battery is replaced always verify the following:

1. Is the battery charging voltage appropriate for the type of use the department will use it for? 14.0–14.4 if battery back-up only, 14.6–14.8 if used only on battery power.
2. Is the battery low and empty indicators correct? (see troubleshooting)

Main Board- When the main board is removed or replaced, verify the following:

1. Is the appropriate software on the board?
2. Are the dip switches set appropriately?
3. Is the A-Tube kinked behind the power supply cable or between the board and chassis?
4. Is the printer cable connected, if applicable?

9.0 Illustrated Parts Listing

9.1 Parts Listing: 8800

PC BOARD

ID #	Part #	Description
1	0330187A	Main Board 8800P
1A	0330244A	Main Board 8800P (Smart Features)
1B	0330188A	Main Board 8800C
1C	0330245A	Main Board 8800C (Smart Features)
1D	0330207A	Main Board 8800MSP (no Neonate)
1E	0330206A	Main Board 8800MS (no Neonate)
2	0310050A	Display Board 8800C/P
2A	0310061A	Display Board 8800C/P (amber MEAN)
2B	0310048A	Display Board 8800MS/MSP
2C	0310063A	Display Board 8800MS/MSP (sys Hi/Lo alarm)
3	X8150030B	Printer Board 8800P,MSP

FRONT PANEL

Front Case Kits are as follows:

Front Case C (8800C units)	Basic unit with no printer
Front Case P (8800P units)	Basic unit with printer
Front Case MS (8800MS or T)	Basic unit, no printer, with tympanic
Front Case MSP (8800MSP or TP)	Basic unit, w/printer, w/tympanic
Front Case SC (8800SC units)	Smart unit (SYS alarm LEDs), no printer
Front Case SP (8800SP units)	Smart unit (SYS alarm LEDs), w/printer
Front Case SMS (8800SMS units)	Smart unit (SYS alarm LEDs), no printer, with tympanic
Front Case SMSP (8800SMSP)	Smart unit (SYS alarm LEDs), w/printer, with tympanic

ID #	Part #	Description
4	3200115C	Front Case without Labels
5	XC2250167A	Sheet Switch 8800P/MSP/TP
5A	XC2200250B	Sheet Switch 8800P/MSP (sys. Hi/Lo alarm)
5B	XC2250168A	Sheet Switch 8800C/MS/T
5C	XC2200251B	Sheet Switch 8800C/MS (sys. Hi/Lo alarm)
6	2200126B	Front Panel 8800C/P
6A	2200181A	Front Panel 8800SC/SP (amber MEAN)
6B	2200171A	Front Panel 8800MS/MSP
7	XC2120577A	Packing Plate
8	3200119B	Paper Cutter Assembly 8800P
9	3200117A	Printer Cover Plate
10	XC7730003A	Rubber Leg, (foot, rubber,8800)
11	XC2120537B	Stopper, L Shape Front Case
12	X4100191A	Hexagon Nut Shaft
13	XC5620003B	Backlit LCD Display

REAR PANEL

Rear Case Kits are as follows:

Rear Case C/TC (8800C or 8800TC)	Basic unit, no printer, no ON/OFF switch
Rear Case C PS (8800C or 8800TC)	Basic unit, no printer, w/ON/OFF switch
Rear Case P/TP (8800P/TP/MSP)	Basic unit, w/printer, no ON/OFF switch
Rear Case P PS (8800P/TP/MSP)	Basic unit, w/printer, w/ON/OFF switch
Rear Case MS (8800T wo/neo switch)	Basic unit, no printer, wo/neo switch
Rear Case MSP (8800TP wo/neo switch)	Basic unit, w/printer, wo/neo switch
Rear Case SC (8800SC/SMS)	Smart unit (SYS alarm LEDs), no printer
Rear Case SP (8800SP/SMSP)	Smart unit (SYS alarm LEDs), w/printer

ID #	Part #	Description
14	3200116D	Rear Case W/O Labels
15	XC2170101C	Slide Bracket
16	4230007B	Knob Slide Base
17	3200122B	Knob w/Shaft
18	X2120538A	Stopper, Rear Case
19	XC2570003B	Sponge Handle
20	XC3200118B	Pole Holder w/Rubber Holder Kit
21	XC2360008B	Rubber Holder
22A	2250050C	Rear Sheet Label 8800P/MSP
22B	2250243A	Rear Sheet Label 8800P/SMSP (with Print Mode)
22C	2250061B	Rear Sheet Label 8800C/MS
22D	2250171B	Rear Sheet Label 8800MSP (no Neonate)
22E	2250172B	Rear Sheet Label 8800MS (no Neonate)
23	XC7240008A	Battery 12 Volt, 2.3 Ah
24	4100185A	Screw for Battery Cover
25	2100529B	Battery Cover
	XBTCVR	Battery Cover w/screws kit

INSIDE

ID#	Part #	Description
27	XC0140016C	Main Chassis
28	6800031A	Power Supply Board-25% Exchange Item
29	6700054A	Power Transformer(115v)
29A	6700055A	Power Transformer(220v)
30	XC7270002A	AC Inlet
31	XC7210031A	Fuse Holder & Cap
33	XC7220002A	Fuse (1 Amp Slow Blow)
35	4100281A	Grounding Terminal
36	4100183B	Support Cord Stop
37	2160073A	Cord Stopper
38	0250046A	Luer Lock for Chassis(M)

ID#	Part #	Description
39	XC2110394C	Sub Chassis
40	6820001A	Printer 8800,BX-5
41	X2120531B	Printer Stand
42	X2120534C	Photo Interrupter Bracket
43	0780002A	Photo Interrupter
44	X4240012A	Roller Guide
45	XC6140390A	Overpressure Switch
46	3210021B	Paper Box
47	X3210022A	Paper Box Base
48	XC2110266B	P, Plate Paper Guide
49	0200023A	Pump w/Pump Nut
51	XC2120861A	Rt. Reinforcement Bracket
52	X2110393B	Pump Bracket
53	0200033A	Bleed Valve
54	0250029A	Air Manifold
54A	X0250048A	Air Manifold (Smart Inflation)
55	3260003B	L-Tube
56	XC75310170	Air-Tube A
57	XC75301170	Air-Tube B
58	XC75310040	Air-Tube C
59	7540005A	Clamp
60	X3260013A	L-Tube D
	XC2120861A	Rt. Reinforcement Bracket
	XC2120862A	Lt. Reinforcement Bracket
	XC2120860A	Slider Reinforcement Bracket
	X7540024A	Valve, Solenoid

TYMPANIC HOUSING PARTS

ID#	Part #	Description
	X3200424A	Left Hinge (Blue)
	X3200423A	Right Hinge (Blue)
6	3200422A	Door, Probe Cover Holder (Clear)
4	3200464A	Honeycomb, Probe Cover Holder
	2270059A	Spacer Honeycomb, Lg. (White)
	3270012A	Spacer Honeycomb, Sm. (Blue)
	2270060A	Spacer Honeycomb, Sm. (White)
	2570010A	Felt Honeycomb (Black)
13	1600206A	Label, Rear Sheet 8000MS (w/interface)
13	1600205A	Label, Rear Sheet 8000G (no interface)

9.2 Accessory Parts List: 8800

COLIN MEDICAL INSTRUMENTS hours of operation are 8 a.m. to 6 p.m. (Central Standard Time), Monday through Friday. Call us for pricing or additional information at 800-829-NIBP (6427).

Description	Order #
Accessories	
Wall Mount	C0610020A
Operation Manual 8800 Series	C1730020A
Service Manual	C1730016B
Inservice Videotape	Call
3.5m gray adult hose	0450010B
3.5m green neonatal hose	0450012B
Printer paper, box (5 rolls)	C1780009A
NIBP calibration test kit	C0690003A
Fetal monitor interface cable	C7110001A
Dust cover	XC1810012A

Description	#/Pkg	Order #
Adapters: 1-Tube to 1 Tube		
Hewlett Packard	25	C0430021A
Physio-Control	25	C0430023A
Spacelabs	25	C0430025A
Marquette (new)	25	C0430027A
Marquette & Propaq (old)	25	C0430029A
1-Tube to 2-Tube Reusable/Disposable Cuffs		
Colin, Datascope N.A.D. (new style-Critikon)	10	C0430022A
Colin, Datascope N.A.D. (old style-Critikon)	10	C0430024A
Dinamap, Spacelabs	2 sets/10 sets	C0430030A
Hose Connectors: 1-Tube to 2-Tube Neonatal		
Colin, Datascope N.A.D.	10	C0430033A
Colin, Datascope N.A.D (without fittings)	10	C0430034A
Reusable Cuff Covers		
Infant	1	C0430041A
Child/small adult	1	C0430042A
Adult	1	C0430043A
Large Adult	1	C0430044A
Thigh	1	C0430045A

Description	Order # 1-tube	Order # 2-tube
Reusable Blood Pressure Cuffs		
Infant	C0430001A	C0430002A
Child/Sm. adult	C0430003A	C0430004A
Adult	C0430007A	C0430008A
Large adult	C0430009A	C0430010A
Thigh	C0430011A	C0430012A
Cuff Assortment Packs		
Reuse. Assort. Pk.	C0430091A	C0430092A
Reuse. Adult Pk.	C0430093A	C0430094A
Reuse. Child Pk.	C0430095A	C0430096A
Disp. Assort. Pk.	C0400081A	C0400082A
Disposable Cuffs		
Large adult/thigh	C0400011A	C0400012A
Adult	C0400013A	C0400014A
Pediatric	C0400015A	C0400016A
Neonate (#4)	C0400017A	C0400018A
Small pediatric	C0400019A	C0400020A
Neonatal Cuffs		
#1	C0400001A	C0400002A
#2	C0400003A	C0400004A
#3	C0400005A	C0400006A
#4	C0400007A	C0400008A
#5	C0400009A	C0400010A
Reusable Cuff Bladders		
Infant	C0430053A	C0430054A
Child/small adult	C0430055A	C0430056A
Adult	C0430057A	C0430058A
Large Adult	C0430059A	C0430060A
Thigh	C0430061A	C0430062A

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9.3 Parts List: 8000MS, 8000IR, 8000N

ID #	Part #	Description
1	3200417A	Base Case
2	3200418A	Right Case
3	3200419A	Left Case
4	3200419A	Probe Cover Case
5	3200420A	IR Detector Plate
6	3200422A	Door
7	3200423A	Door Hinge Right
8	3200424A	Door Hinge Left
9	3200425A	Genius Latch
10	3200426A	Latch Guide
11	3200427A	Latch Spring
12	7700017A	Magnet
13	1600148A	Rear Label
14	2150347A	Serial Number Plate
15	7730003A	Rubber Foot
16	6441030A	IL-2S
17	0450027A	Curl Tether
18	7100069A	Ground Wire 1
19	7100070A	Ground Wire 2
20	7100071A	Ground Wire 3
21	7140060A	LED, 8800IR
22	0370065A	Main PC Board
23	0370069A	OPIC Unit
24		Caution Label

9.4 Parts List: FILAC

ID #	Part #	Description
1	7774-005909	Printed Circuit Board Assembly
2	7774-101971	(2) "AA" Battery
3	7774-105717	Normal/Direct Mode Switch Assembly
4	7774-701077	Touch Panel
13	7774-178003	Mylar Overlabel
14	7774-400233	(2) No. 6 Plain Washer
15	7774-303213	(3) No. 4 - 10 x 1/4" Self Tap Screw
16	7774-303783	(2) No. 4 - 10 x 1 1/2" Self Tap Screw
17	7774-304286	(2) Flathead Tubular Rivet
18	7774-105725	Battery Clip Assembly
20	7774-304773	(2) Stainless Steel Dowel Pin
23	7774-304807	(2) No. 2 - 32 x 5/32" Self Tap Screw
24	7774-304815	(3) No. 3 - 28 x 5/16" Self Tap Screw
25	7774-304823	(2) No. 4 - 24 x 7/32" Self Tap Screw
26	7774-401793	Neck Strap
28	7774-807163	Instruction/Serial Number Label
29	7774-307099	Switch Actuator
30	7774-309756	Case Top
31	7774-309764	Case Bottom
32	7774-309889	Case Bolt
33	7774-106053	Battery Door Assembly
34	7774-309905	Fascia
35	7774-309913	Right Battery Compartment Mount
36	7774-309921	Left Battery Compartment Mount
37	7774-309939	Probe Box Retainer
38	7774-310259	F-2000 Labels
38A	*	Dip Switch Label
38B	*	Battery Label
38C	*	Copyright Label
38D	*	Direct/Normal Label
39	7774-106079	Case Top with Neck Strap Assembly (items 14, 17, 26 & 30)

Part of Item 38

NOTE: Parts available through Kendall.

10.0 Schematics

10.1 Block Diagram: 8800

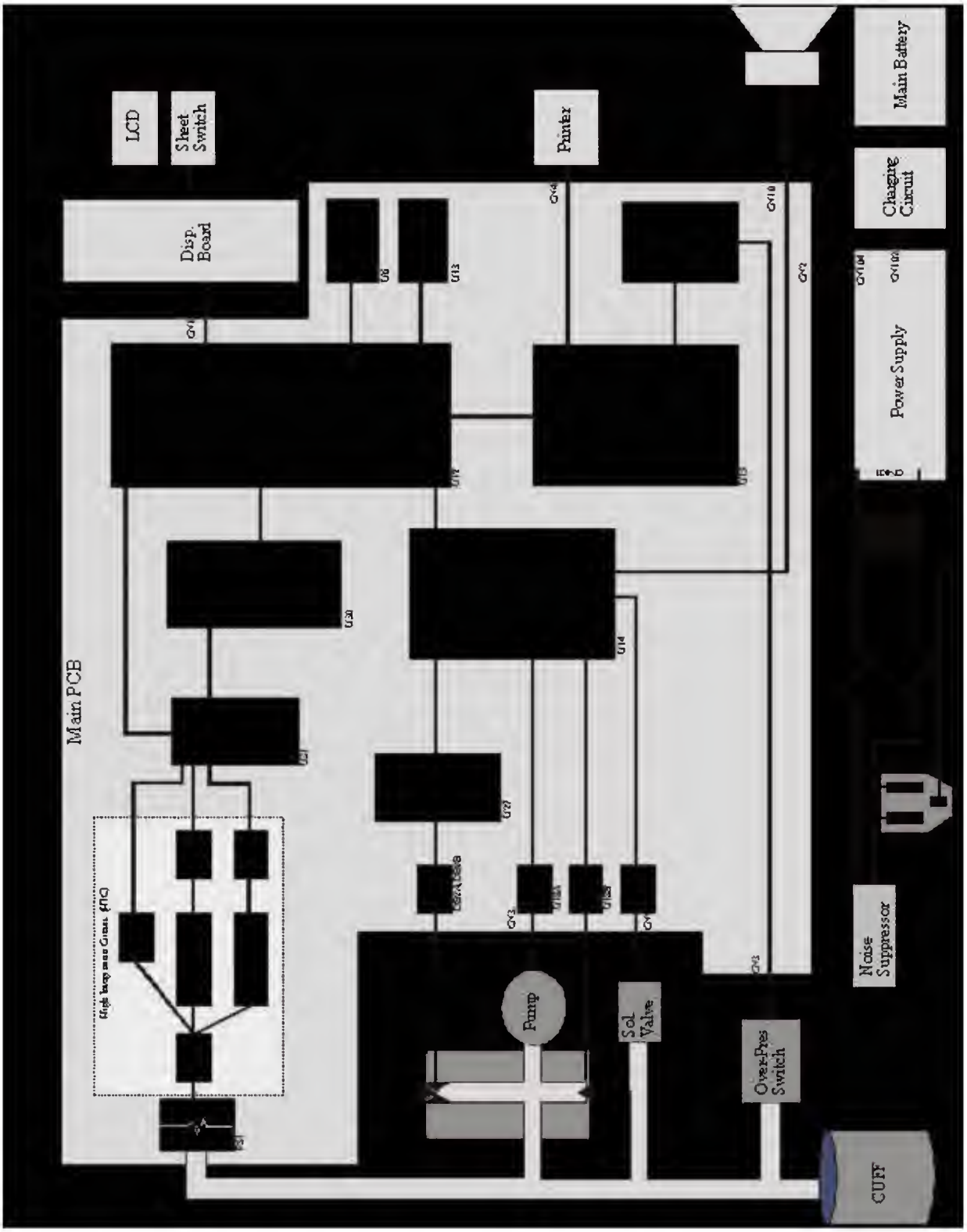

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Diagram of 8800 (without Smart Features)

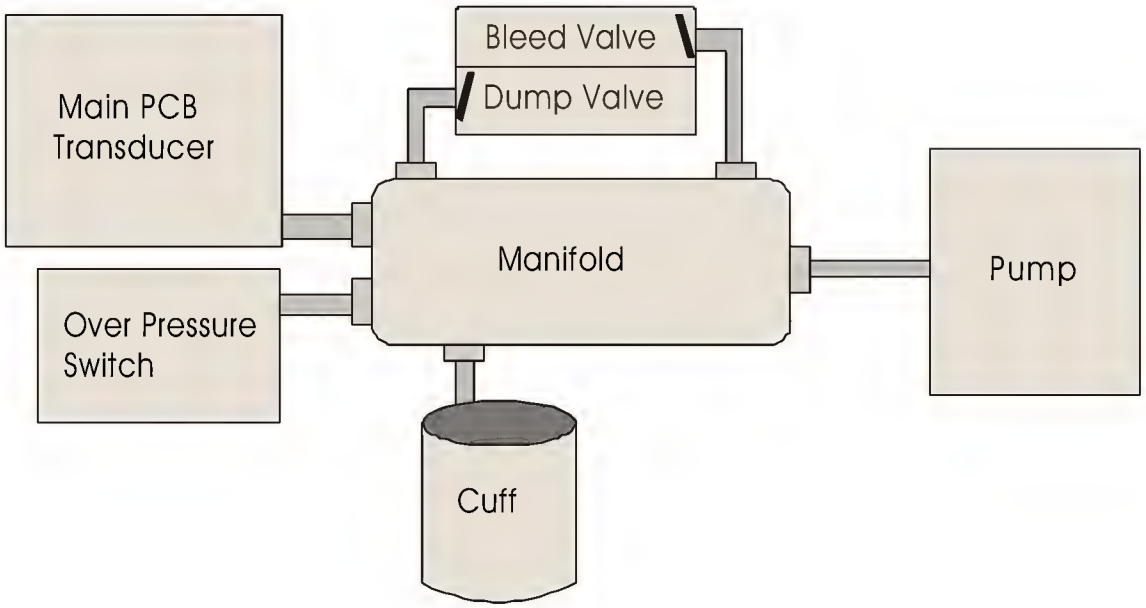
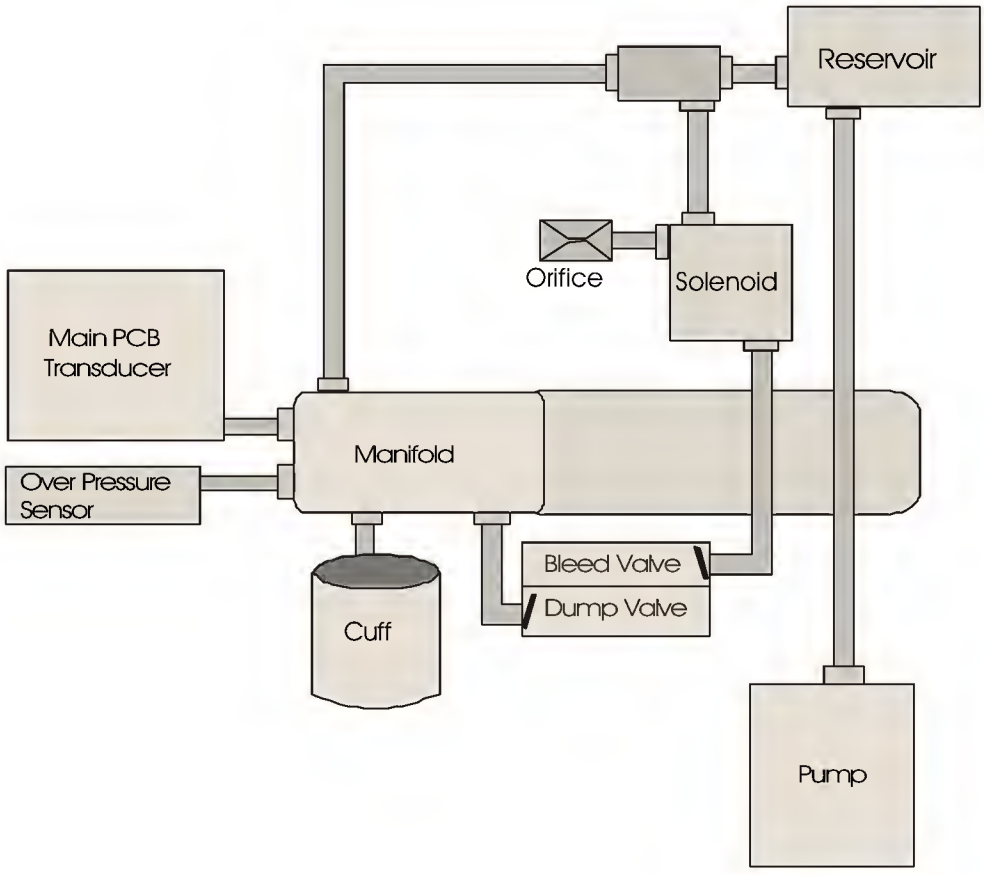
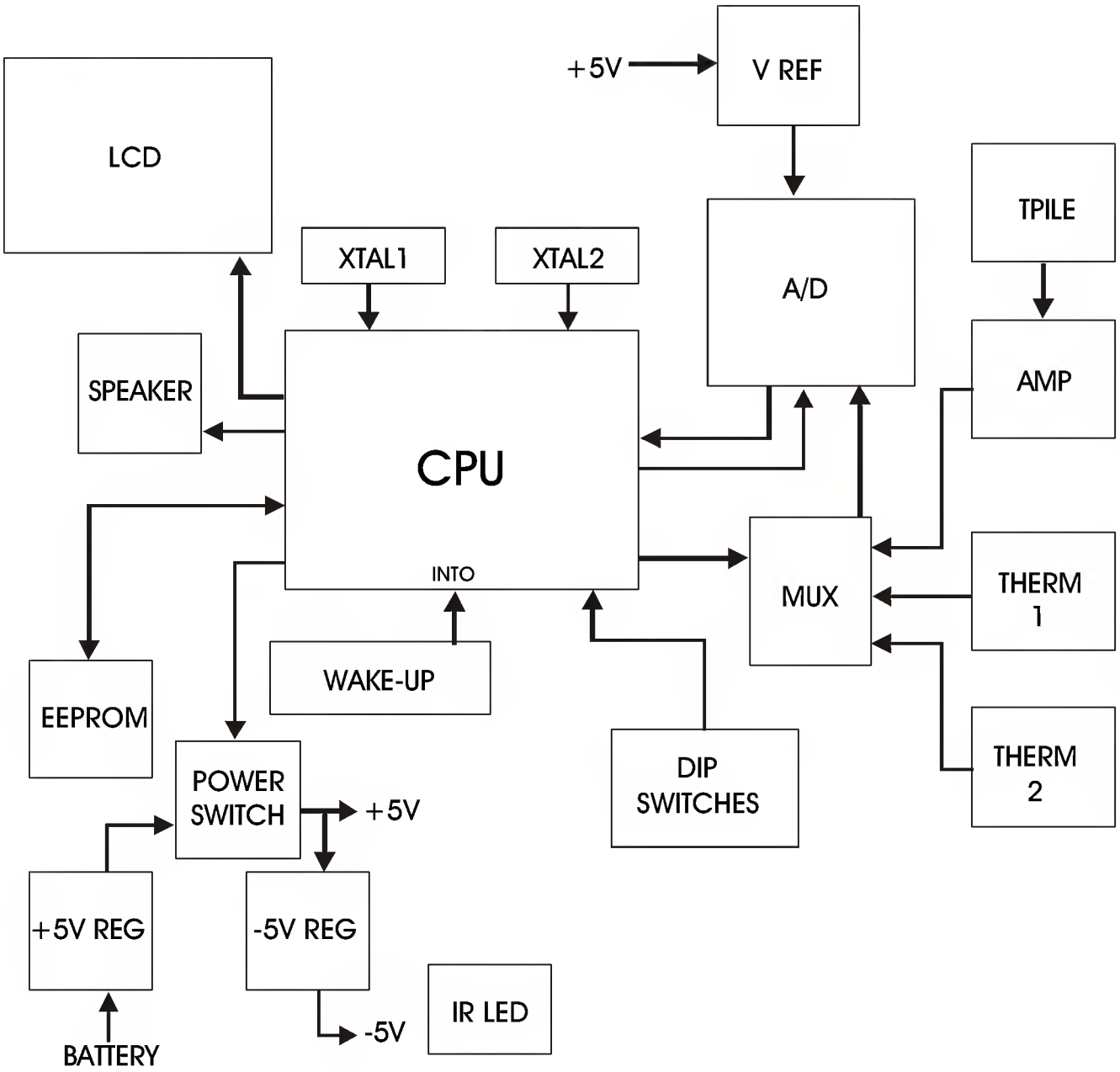


Diagram of 8800 (with Smart Features)



10.2 Block Diagram: Genius



11.0 Specifications for Press-Mate, Genius and FILAC

11.1 Environmental Requirements: 8800

1.	Power Supply	120 Volts AC
2.	Power Consumption	33 VA
3.	Operating Temperature	10 to 40 ℃
4.	Operating Humidity	15 to 95%
5.	Storage Temperature	-20 to 70 ℃
6.	Storage Humidity	5 to 95%
7.	Nominal Life	6 years

11.2 Functional Specifications

1.	Pressure Display Range		10 to 300 mmHg
2.	Display Accuracy		Within 2% range
3.	Inflation speed		2.8 to 7.3 seconds (693 cm^3 air chamber 0 to 250 mmHg)
4.	Deflation speed at pressures indicated:		
	Pressure		Speed (mmHg/sec.)
	240		4.6 to 6.2
	160		4.6 to 6.2
	80		3.3 to 5.0
	40		2.6 to 4.4
5.	Withstand voltage (between unit and primary supply)		1000 to 1250 V
6.	Leakage current		<100 uA
7.	Earth resistance		<0.1 ohm
8.	Withstand line noise voltage		
	Pulse width:	200 ns	> 1 kV
		500 ns	> 1 kV
		100 ns	> 1 kV
9.	Withstand static noise voltage		
	Normal operation guaranteed at <10 kV		

11.3 Thermal Printer

1.	Character size	2.4 x 1.5
2.	Paper width	58 mm
3.	Print width	46.1 mm
4.	Print speed	46 cps
5.	Thermal printing paper	C1780009A

11.4 Output Terminal DSUB-15

PIN NO.

1	F.GND
2	Tx (RS232C level output)
3	Rx (RS232C level output)
4	RTS (RS232C level output)
5	CTS (RS232C level output)
6	NC
7	GND
8	NC
9	+5 V
10	Tx (TTL output)
11	Rx (TTL output)
12	RTS (TTL output)
13	CTS (TTL output)
14	+12 V ON/OFF
15	R/B (TTL)

11.5 Physical Specifications

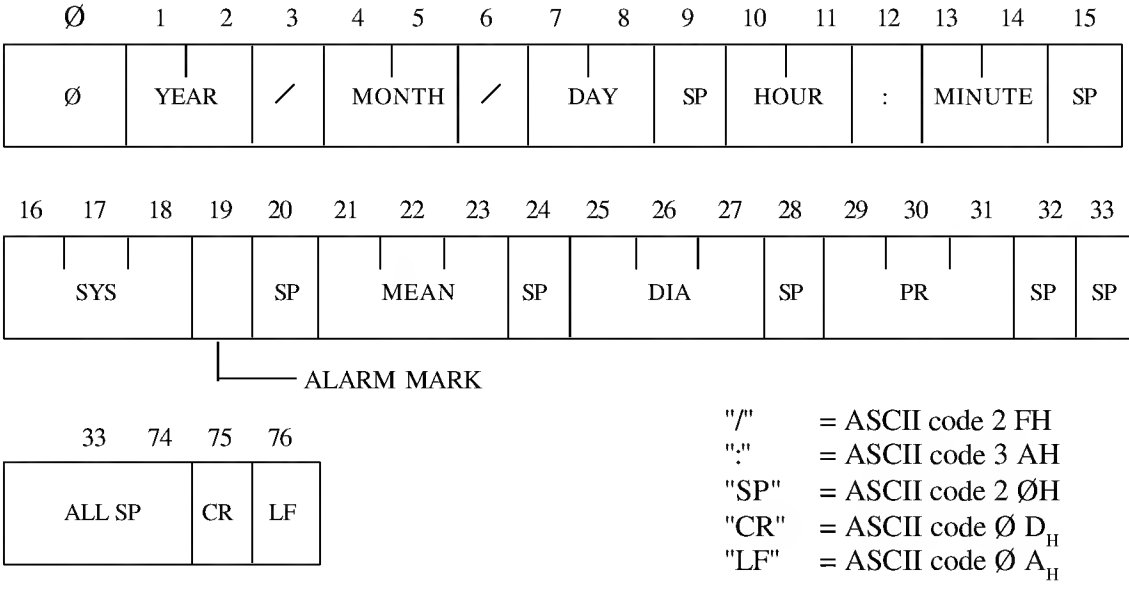
Measurement Method	Oscillometric
Display Method	LED display (for actual measurement data) LCD (stored data, error messages, and alarm settings)
Pressure Detection	Semiconductor pressure sensor
Inflation Method	Diaphragm pump driven by a DC motor
Display Range	Pressure: 10-300 mmHg Pulse Rate: 30-240 bpm
Outside Dimensions	170 (W) x 170 (D) x 228 (H) mm
Weight	Approximately (4.8Kg)
Power Supply	AC 120V±10% 60Hz
Battery	12V, 1.9AH
Battery Life	4 hrs @ 5 min. interval measurements
Storage Temp. Range	-20ºC to +70ºC (-20ºC to +40ºC for battery)

11.6 Standard Accessories

(1) Disposable Adult Cuff
(1) Adult Cuff (12 cm in width)
(1) 3.5 m pressure hose
(2) Paper Roll (for units with printers)
(1) Paper Shaft (for units with printers)
(1) AC-power cord
(2) Boxes Patient Pack Genius Probe Covers
(1) Rolling Stand
(1) Dust Cover
(1) Operations Manual

11.7 Communication Specifications

a. Asynchronous
b. 4800 bps
c. 1 start bit
d. 8 data bits
e. Even Parity
f. 1 Stop Bit
g. Ready/Busy Control by RTS/CTS Signal
Data can be received by Press-Mate when RTS signal level is HIGH. Data can be transmitted by Press-Mate when CTS signal level is HIGH.
h. RS-232C ouputs data when Temp-Mate is connected.
i. When a measurement is completed, data is output according to the format in the following diagrams:



"/" = ASCII code 2 FH
":" = ASCII code 3 AH
"SP" = ASCII code 2 ØH
"CR" = ASCII code Ø D_H
"LF" = ASCII code Ø A_H

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ALARM MARK
Over higher limit - ">" = ASCII code 3 E_H
Under lower limit - "<" = ASCII code 3 C_H
Without alarm - ASCI code 2 $Ø_H$

SYS, MEAN, DIA, PR – Each value consists of 3 bytes in ASCII code.

YEAR, MONTH, DAY, HOUR, TIME – Each value consists of 2 bytes in ASCII code.
YEAR consists of 2 bytes of most significant digits of the year, e.g. 1992 = "92".

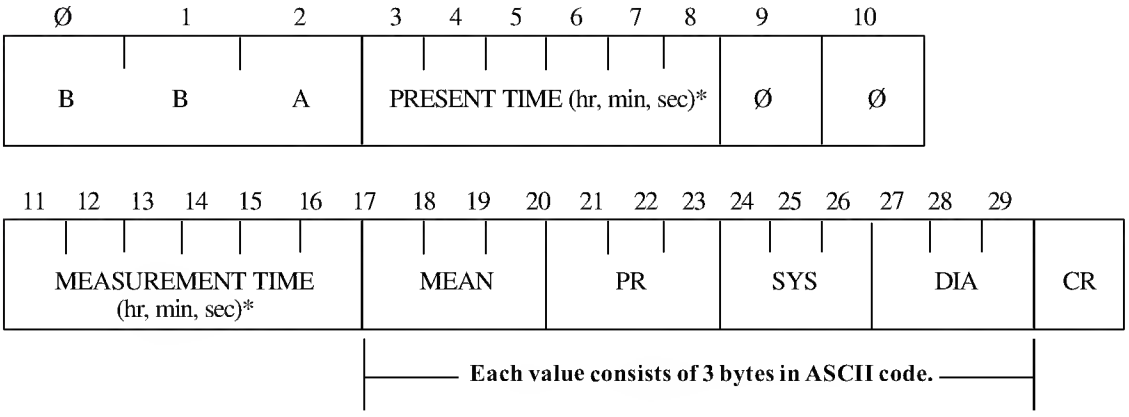
> **NOTE**: The Mean Blood Pressure value is calculated each measurement, but is not displayed on the front panel for 8800 MS/MSP only.

Output Terminal DSUB-15 (on rear panel; Corometrics Version–Dip switch No. 4 = OFF)

1. Communication Specification
   a. 600 bps
   b. 8 data bits
   c. None parity
   d. 1 stop bit
   e. Ready/Busy control by CTS signal (Data can be transmitted from Press-Mate when CTS signal level is HIGH).

2. Output

When a measurement is completed, data is output according the following format.


Ø 1 2 3 4 5 6 7 8 9 10
B B A
PRESENT TIME (hr, min, sec)*
Ø
Ø
11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29
MEASUREMENT TIME
(hr, min, sec)*
MEAN
PR
SYS
DIA
CR
Each value consists of 3 bytes in ASCII code.

***Each value consists of 2 bytes in ASCII code.**

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11.8 Specifications: Genius

Accuracy: ±0.2ºF (±0.1ºC), 96ºF - 102ºF
Other points as specified by A.S.T.M

Temperature Range: 60ºF to 110ºF (15.5ºC to 43.3ºC), ºC or ºF

Ambient Temperature Operating Range: 60ºF to 104ºF (15.5ºC to 40ºC)

Storage Temperature Range: -4ºF to 122ºF (-20ºC to 50ºC)

Response Time: Approximately 1 to 2 seconds

Primary Mode: Tympanic

Resolution: 0.1ºC (0.1ºF) displayed on LCD

Power: One 9-volt Alkaline or Lithium battery

Battery Life: Approximately 5000 temperatures

Low Battery Warning: 2 levels on LCD screen
Level 1 – "Replace battery as soon as practical"
Level 2 – "Replace now, thermometer will not operate"

Optional Temperature Conversion: User-programmable for rectal, oral, or core equivalents (ºC or ºF)

Unique Features: Incorporates 15-second pulse timer. Tone generator in surface mode. Instant "In-Service Menu System (IMS)" prompts on method of use via LCD screen. May be recalibrated at user site using optional calibrator.

Size of Probe: 8.5"L x 2.2"W x 3"H

Weight of Probe: 7 oz.

Patient Pack Disposables: 21-probe covers

11.9 Specifications: FILAC

Weight: Approximately 19 ounces (excluding probe)

Dimensions: Approximately 2 3/4"H x 3/14"W x 6 1/16"L (excluding probe)

Measurement Range: 90ºC to 110ºF (32º to 43ºC)

Display Range: ± 0.1ºF or ±0.1ºC

Ambient Operating Temperature: 60º to 90ºF (15.6º to 32ºC)

Accuracy: Meets or exceeds A.S.T.M. standard E1112

> **NOTE**: When using a liquid bath to test the accuracy of the predictive mode, correct the final temperature as follows to compensate for the difference between in vivo and in vitro conditions.

CENTIGRADE

Range	Subtract
32.0º to 41.0º	0.6º
>41.0º	0.5º

FAHRENHEIT

Range	Subtract
89.6º to 102.0º	1.1º
102.1º to 106.0º	1.0º
>106.0º	0.5º

Pulse Timer: 15 to 30 seconds

Batteries: (2) AA cell 1.5V Alkaline

12.0 Press-Mate 8800SAT/SATP

12.1 Operations

Taking a Reading

1. Once the appropriate sensor has been applied to the patient, turn the unit on. The N-20P automatically tests its circuitry and lights the entire display. If a problem is detected, an error message is displayed.

> **NOTE**: During operation, the constant pitch beeper sounds once for each pulse, and the pulse amplitude indicator reflects pulse strength at the sensor site. If no sensor is detected, dashes are displayed.

2. During the self-test, check whether PR ON or PR OFF is displayed. To select the printer option required, push the Printer ON button, also use this button to turn the printer off.

3. To turn the N-20P off before the measurement cycle ends, rapidly press the measure button two times.

Installing Batteries

The N-20P operates on four 1.5 V alkaline "C" cell batteries. Do not use off-the-shelf rechargeable batteries; this type of battery can cause the low battery indicator to be inaccurate.

1. Remove the battery access door by pressing the battery compartment access door latch.

2. Install four alkaline "C" cell batteries. Be sure to observe the polarity indicator sticker.

3. Replace the battery cover access door.

Loading/Clearing Printer Paper

The N-20P uses a thermal paper that can show printed characters on one side only. Make sure that the paper roll is correctly installed; always refer to the graphical instruction label found on the paper roll.

1. Press down and outward on the top of the paper compartment door to remove it.

2. Feed the paper into the paper compartment slot; refer to the graphic label for orientation.

3. Press and hold the ADV button until the end of the paper appears at the paper exit slot.

4. Replace the paper compartment door.

If the paper jams either during the loading process or during printing, proceed as follows:

1. Remove both the paper door and the printer-head access cover.

2. Firmly grab and pull the paper roll backward – out and away from the print head – observe the print head access to determine whether or not the paper escaped from the jammed position.

3. If paper remains jammed between the print head and printer, press the ADV button; the jammed paper may work its way out. If the paper remains jammed, and the printer drive does not advance the paper, manually advance the drive gear on the side of the printer to free the paper.

4. If these attempts fail to free the jammed paper, remove the printer from the unit to gain full access (see Disassembly Procedure).

Setting Date and Time

The following code letters and number appear in both Oxygen Saturation and Pulse Rate display fields. The symbol "xx" represents information in the Oxygen Saturation display field and "yy" represents information in the Pulse Rate display field.

Begin this procedure by first removing any sensor from the instrument.

1. Switch on the N-20P and allow the unit run POST.

2. When dashes appear in the Oxygen Saturation and Pulse Rate displays, press the D/D (day/date) button once. At this point, the Oxygen Saturation display field shows "txx", with "t" representing time; "xx" representing hours, and "yy" representing minutes. Note that "xx" (hours) is flashing.

3. Press the ADV (advance) button repeatedly until the correct hour is displayed.

4. Press the D/D button once. Note that "yy" (minutes) is now flashing.

5. Press the ADV button repeatedly until the correct minute is displayed.

6. Press the D/D button. At this point, the Oxygen Saturation display field shows "dxx", with "d" representing date; "xx" representing the month and "yy" representing the date. Note that "xx" (month) is flashing.

7. Press the ADV button repeatedly until the correct month is displayed.

8. Press the D/D button once. Note that "yy" (date) is flashing.

9. Press the ADV button repeatedly until the correct date is displayed.

10. Press the D/D button. At this point, the Oxygen Saturation display field shows "Yxx", with "Y" representing "year". Note that "xx" (year number) is flashing.

11. Press the ADV button repeatedly until the correct year number is displayed.

12. Press the D/D button once. The N-20P turns itself off within 5 seconds.

13. Date and time are now correct. Check by switching on the N-20P with the printer enabled. After the N-20P executes its POST, the printer prints the spot check mode header with the correct date and time.

Replacing the Real-Time Clock (RTC) Battery

The socket for the RTC battery (BTI) is located on the auxiliary PCB at grid location 5D. Typical life of the clock battery is 5 years.

> **Caution**: After replacing and RTC battery, switch the instrument, on then immediately switch it off; this action will prevent possible damage to the RTC voltage circuit.

1. Disassemble the N-20P (see "Disassembly Procedure")
2. Using a thin flathead screwdriver, gently pry the RTC battery from its socket.
3. Insert a new battery into the socket, observing the polarity indication (socket's clip and battery's flat side are positive)
4. Re-assemble the unit.
5. Switch on the instrument, then immediately switch it off (the RTC voltage circuit requires this step to prevent possible damage to the unit). The instrument is now ready for normal operation.
6. Reset the clock (see "Setting Date and Time").

Replacing the PROM

A one-time-programmable PROM memory chip contains the system operations and diagnostic software. This chip (U15) is located in a socket on the main PCB. If software updates are made available from the factory, or if a problem with this chip is suspected, contact Nellcor's Technical Services Department of Nellcor's local representative for information about a replacement chip.

1. Disassemble the N-20P (see "Disassembly Procedure").
2. After noting the chip's orientation, use a PLCC extraction device to remove the chip from its socket on the main PCB.
3. Carefully insert the replacement chip into its socket. *Ensure the chip is correctly oriented.*
4. Re-assemble the unit.

> **Note the alignment marks:** a small dot at the top of the chip and a small triangle at the top edge of the socket should match up. Another key to ensuring correct orientation of the chip and socket is the notched corner of the PROM is to be located at the top left of the socket.

Replacing Fuses

Two fuses (F1 and F2) are located on the auxiliary PCB. Fuse F1 may open to protect the CPU and its associated components from damage if the power supply malfunctions. Fuse F2 may open to protect the printer from damage due to excess voltage if the printer head jams or has been physically damaged. Refer to the auxiliary PCB schematic for the locations of F1 and F2.

Replacing the DB-9 Connector

1. Disassemble the N-20P; the connector is on the main PCB at grid location 3A.

2. Using a low-power soldering iron, unsolder the connector from the PCB and remove it. *Save all Teflon tubing, ferrite blocks, and insulating materials for the replacement connector.*

3. Install ferrite blocks between plastic lead spacer on the connector and the PCB.

4. Insulate connector pin numbers 2, 3, and 5 with Teflon tubing, and insert inside ferrite block.

5. Add insulating material between each end of ferrite block and PCB, and secure with Loctite glue.

6. Solder new connector to PCB and visually check PCB for stray drops of solder before re-assembling.

7. Switch on the N-20P and test the connector with a patient sensor.

Adjusting Printer Darkness

> **CAUTION**: Adjust the printer darkness setting until the lightest legible print is visible. Setting the print darker than this could reduce printer-head life.

Although the N-20P is designed to automatically compensate for conditions that might influence the quality of the printout, the user may want to adjust the print darkness. The normal darkness setting is set at the factory; this setting maximizes both readability and print head life.

1. Switch on the N-20P in spot check mode. (Spot check mode is started by depressing the instrument measure button once.)

2. Simultaneously press and hold the ADV and ON buttons for 2 seconds. If these buttons are not pressed at the same time, two audible beeps will sound and the N-20P wither advances the paper or switches off, depending on which button press is first sensed. If the buttons are pressed at the same time, a single audible beep will sound, "Pr SEt" is displayed, and the printer prints one of the following 6 lines:

PRINTING LIGHTER	(10% lighter than normal darkness)
PRINTING LIGHT	(5% lighter than normal)
PRINTING NORMAL	(normal darkness)
PRINTING DARK	(5% darker than normal)
PRINTING DARKER	(10% darker than normal)
PRINTING DARKEST	(15% darker than normal)

> **NOTE**: The parenthetic line description is not printed, and button presses are ignored whenever the printer is printing.

3. Press the ADV button to change the darkness setting. The printer prints a line with each button press, and the setting increments from lighter to darkest and then wraps back to lighter.

4. Allow the N-20P to switch off (about 30 seconds). The last printer darkness setting is remembered when the N-20P is switched back on. Test this by repeating the procedure and skipping step 3.

12.2 Theory of Operation for N-20P

Overview

The N-20P is based on the principles of spectrophotometry and optical plethysmography. Optical plethsymography uses light absorption technology to reproduce wave forms produced by pulsatile blood. The changes that occur in the absorption of light due to vascular bed changes are reproduced by the pulse oximeter as plethysmographic wave forms.

Spectrophotometry uses various wavelengths of light to qualitatively measure light absorption through given substances. Many times each second, the N-20P passes red and infrared light into the sensor site and determines absorption. The measurements, which are taken during the arterial pulse, indicate absorption by arterial blood, non-pulsatile blood, and tissue.

By correcting "during pulse" absorption for "between pulse" absorption, the N-20P determines red and infrared absorption by pulsatile arterial blood. Because oxyhemoglobin and deoxyhemoglobin differ in red and infrared absorption, this corrected measurement can be used to determine the percent of oxyhemoglobin in arterial blood: SpO_2 is the ration of correct absorption at each wavelength.

Functional Versus Fractional Saturation

Then N-20P measures functional saturation, that is, oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. It does not detect significant levels of dyshemoglobins. In contrast, some instruments such as the IL282 Co-oximeter measure fractional saturation, that is, oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including dyshemoglobins.

Consequently, before comparing N-20P measurement with those obtained by an instrument that measure fractional saturation, measurements must be converted as follows:

$$\text{functional saturation} = \text{fractional saturation} \times \frac{100}{100-(\%\ \text{carboxyhemoglobin} + \%\ \text{methemoglobin})}$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PaO_2), the calculated value may differ from the N-20P SpO_2 measurement. This is because the calculated saturation may not have been corrected for the effects of variables that can shift the relationship between PaO_2 and saturation.

Figure 12.1 illustrates the effect that variations in pH, temperature, partial pressure of carbon dioxide (PCO_2), and concentrations of 2,3-DPG and fetal hemoglobin may have on the oxyhemoglobin dissociation curve.

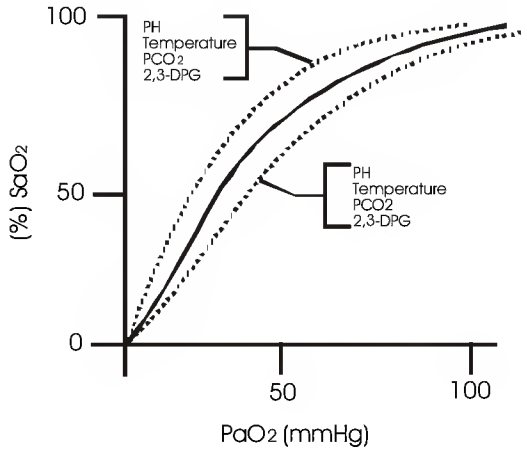

Figure 12.1 Oxyhemoglobin dissocation curve

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Overview

This section provides a detailed explanation of N-20P operation using block diagrams and circuit schematics.

The N-20P consists of three main components:
1. The N020P main PCB schematic diagram.
2. The N-20P auxiliary PCB schematic diagram.
3. The N-20P flex circuit schematic diagram.

The relationship between these components and their interconnection is illustrated in the overall block diagram. The main component has been divided into the following subsections:

SpO_2 Analog Circuitry Block Diagram (Figure 12.3)
Analog circuitry has high signal sensitivity and reduced susceptibility to noise. Its design allows for a wide range of input signal levels and a broad range of pulsatile modulation. The SpO_2 analog circuit consists of four subsections:

1. Sensor output/LED control, where the CPU controls the gain of both LEDs so that signals received at the input amplifier are in its acceptable dynamic range;

2. Input signal conditioning, where sensor output current is converted to voltage;

3. Signal gain, where the separated LED signals are amplified so their current levels are within the A/D converter's acceptable range; and, AC ranging, where DC offset is eliminated from each LED signal.

Digital Circuitry Block Diagram (Figure 12.4)
The diagram shows the N-20P hardware and circuits, which include: the CPU and system memory, the power supply and power control circuitry, user controls, display and ambient light sensors, audio output, thermal printer and ambient temperature sensor, and the real-time clock.

Display Control Block Diagram (Figure 12.5)
The N-20P display is controlled by the display control circuitry. A sensor is used to measure ambient light. During low light conditions, the display backlight, an electroluminescent device, is automatically switched on.

Power Supply Block Diagram (Figure 12.6)
Power supply circuitry is located on the auxiliary PCB and consists of four subsections:

1. Four "C" size batteries that provide 4-6 VDC;

2. Power control circuitry that senses a press of the measure button and switches power on;

3. Power shut-off circuit that controls power to all circuits except the power control circuit; and

4. Power supply circuits include: a regulated power supply at 5 VDC, unregulated power supplies of -5 VDC, 10 VDC, and 12 VDC, and a high voltage power supply of 70 VDC.

Printer Control Block Diagram

Printer circuitry is divided into two subsections: the printer interface and the printer flex circuit. The printer interface circuitry is present on all models, but is disabled by software in the N-20. The printer flex circuit is added when a printer is present.

Definition of Terms

Analog to Digital (A/D) converter – The CPU has a 10-bit A/D converter on board. Up to eight different analog inputs can be provided to the A/D for measurement.

Central Processing Unit (CPU) – An intel 80C196KC 16-bit microcontroller. The CPU sends and receives control signals to the SpO_2 analog section, display, and optional printer.

Content Addressable Memory (CAM) – The CPU controls the HSO lines with the CAM. CAM is software controlled and programmed with events scheduled relative to one or two internal timers.

High Speed Outputs (HSO) – The 6 HSO lines control most of the timing of the LED signal pulse and the demodulation of the received signal.

Input and Output (I/O) – Digital lines that are used by the CPU to read in data and output data.

Light Emitting Diodes (LEDs) – Two LEDs are used in Nellcor oximetry sensors. Light is transmitted through body tissue and received by a photodetector circuit that converts it to photocurrent. The two wavelengths, which are used for calculation of pulse rate and oxygen saturation in blood, are transmitted at the following wave lengths:

infrared (IR) light at = 915 nanometers
red light at - 660 nanometers

Pulse width Modulation (PWM) – The three 8-bit PWM outputs can be software controlled; their duty cycle can be changed from 0-255/256 of the total pulse duration. PWM frequency is the crystal frequency of the CPU, which is 10 MHz divided by 1024. The PWMs control the gains within the analog circuit.

RCal – Sensor RCal value is a resistance value specific to an individual sensor. This value is used by the software during oxygen saturation computations to maximize accuracy.

Real-Time Clock (RTC) – The RTC is used with the optional printer to track time and date for printouts.

Overall Block Diagram

Exclusive of covers, button, and external connectors, the N-20P consists of three main components: the main PCB, the auxiliary PCB, and the display assembly and analog shield.

Main PCB – contains the SpO_2 analog circuitry; the CPU; support memory circuits; sensor circuits for ambient light, temperature, and battery voltage; the check battery circuit; a serial data port; and some display control circuits.

Auxiliary PCB – contains the power supply circuitry; the display driver circuits; the real-time clock; the interface circuitry for the printer flex circuit board (which is not used unless a printer is present); and audio output hardware.

Display and Analog Shield Assembly – this assembly connects to the main PCB by flex circuits. A metal shield shrouds the SpO2 analog circuits on the main PCB to protect them from EMI. An integrated electroluminescent backlight illuminates the display under low light conditions.

The N-20P has an additional printer control board (printer flex circuit), and printer hardware. The following block diagram shows the relationship between these components.

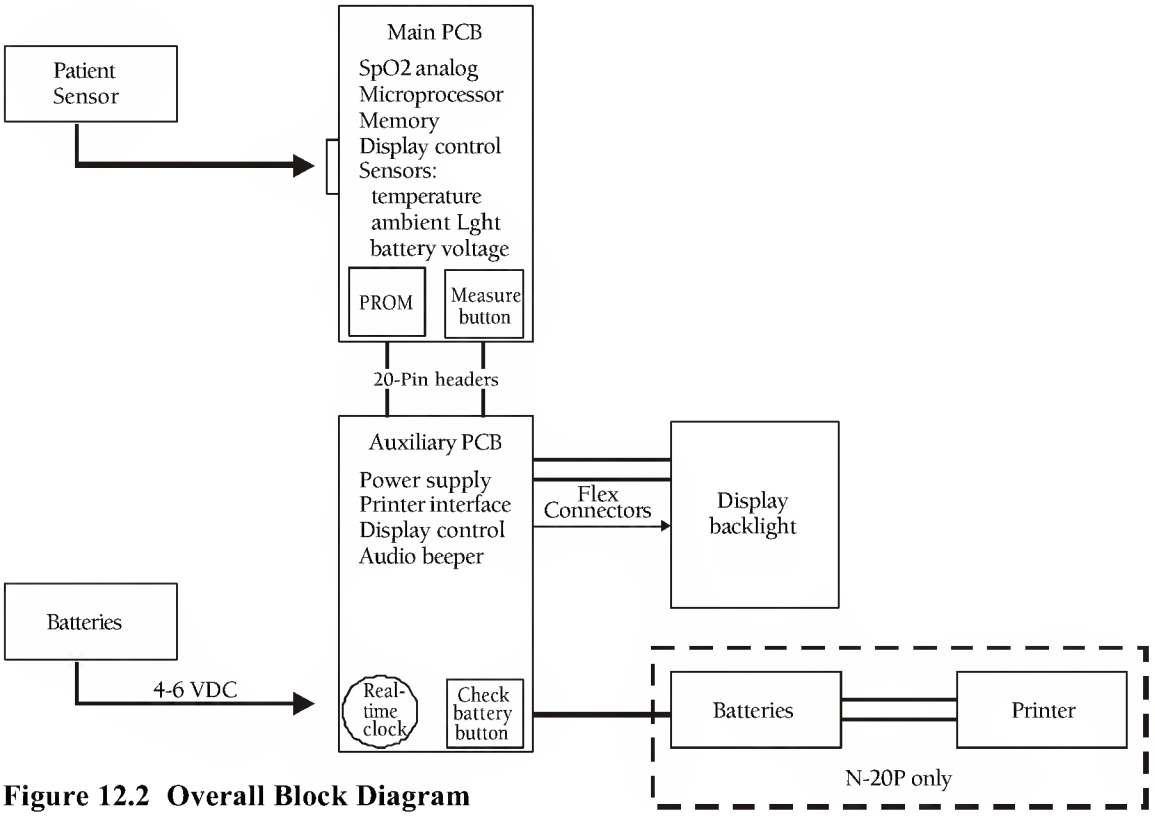

Figure 12.2 Overall Block Diagram

SpO2 Analog Circuitry

This subsection describes the SpO_2 analog hardware. The analog circuitry has high signal sensitivity and reduced susceptibility to noise. Its design allows for a wide range of input signal levels and a broad range of pulsatile modulation. The SpO_2 analog block diagram (Figure 12.3) consists of four subsections:

Sensor/output LED control – The CPU controls the gain of both LEDs so that signals received at the input amplifier are within an acceptable dynamic range. Signal channel gain may also need to be increased. The CPU uses PWM lines to control LED current level or to amplify the signal channel.

Input conditioning – Sensor output current is converted to voltage. A demodulation circuit minimizes the effects of other light sources and stray frequency inputs. Because the IR and RED signals are at different current levels, the two LED signals are demultiplexed and separately amplified, so they can be compared with each other. Two circuits handle the demultiplexing by alternately selecting LED signals using switches. Filters then remove noise and smooth the signals before sending them to the amplifiers.

Signal gain – The separated LED signals are amplified so that their current levels are within the A/D converter's acceptable range. The signals are filtered to improve the signal-to-noise ratio, and clamped to a reference voltage.

AC ranging – DC offset is eliminated from each LED signal. An analog switch sets the mean signal value to the mean of the A/D converter range, and the AC modulation is superimposed on that DC level. Then, each AC signal is amplified and filtered to eliminate residual effects of the PWM modulations. Finally, these two signals are input to the CPU A/D converter.

The relationship between these subsections is shown in the following block diagram.

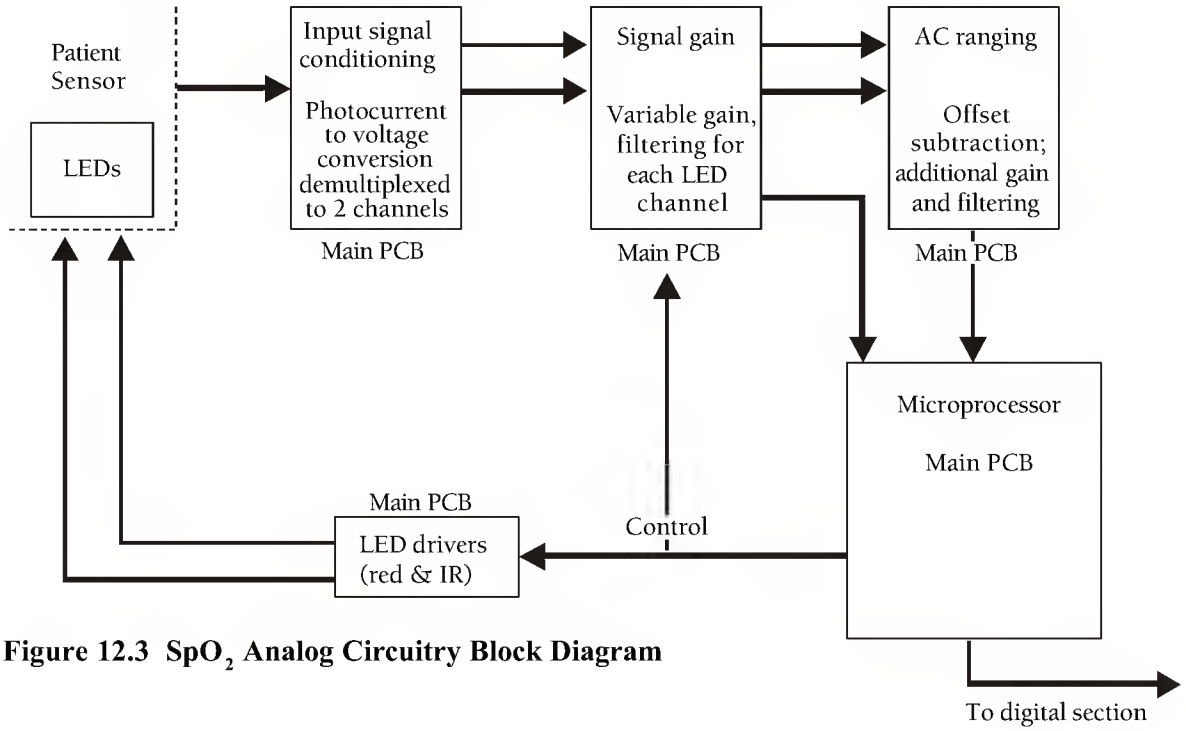

Figure 12.3 SpO_2 Analog Circuitry Block Diagram

Sensor Output/LED Control

The SpO_2 analog circuitry provides control of the red and IR LEDs such that the received signals are within the dynamic range of the input amplifier. Because excessive current to the LEDs will induce changes in their spectral output, it is sometimes necessary to increase the received signal channel gain. To that point, the CPU controls both the current to the LEDs, and the amplification in the signal channel.

At initialization of transmission, the LEDs' intensity level is based on previous running conditions; and, the transmission intensity is adjusted until the received signals match the range of the A/D converter. If the LEDs reach maximum output without the necessary signal strength, the PWMs will increase the channel gain. The PWM lines will select either a change in the LED current or signal gain, but will not do both simultaneously.

The LED circuit switches between red and IR transmission and disables both for a time between transmissions in order to provide a no-transmission reference. To prevent excessive heat build-up and prolong battery life, each LED is on for only a small portion of the duty cycle. Also, the frequency of switching is well above that of motion artifact and not a harmonic of known AC transmissions. The LED switching frequency is 1.485 kHz. The IR transmission alone, and the red transmission alone will each be on for about one-fifth of the duty cycle; this cycle is controlled by the HSO's of the CPU.

LED Drive Circuit

The IR and red LEDs are separately controlled with their drives currents multiplexed over two shared wires. Current to the IR LED is in the range of 4.3-50.0 mA; and, current to the red LED is in the range of 6.5-75.0 mA. Currents are limited to less than 100 mA for two reasons: (1) slight excess current can potentially change the emission characteristics of the LEDs, and (2) large excess current could create excessive heat at the sensor site.

The IR/red LED transmission signal (HSO1 of the CPU) is fed into the select inputs of the triple single-pol-double-throw (PDT) analog multiplexing switch U10, causing either the IR or the red LED transmission to be enabled.

PWM1, which is filtered by the network of R44, R52, and C38, is input to the LED drive circuit switch U10, and controls the magnitude of the IR LED current supply.

PWM2, which is filtered by the network of R43, C36, R53, and C39, is also input to U10, and controls the red LED current magnitude.

Two NPN transistors (Q1 and Q2) act as current sources for the IR and red LED outputs. Two PNP transistors (Q3 and Q4) act as switches between the IR and red LED output lines. Transistor Q5 acts as an LED drive current limiter; it clamps output of the current regulator circuit to the required level. If any resistor in the LED drive circuit fails, current to the LED will still be limited to a safe level.

The RSENS line senses the RCal value and enables the CPU to make the proper calculations based on the type of sensor being used.

Input Conditioning

Input to the SpO_2 analog circuit is the current output of the sensor photodiode. In order to condition the signal current, it is necessary to convert the current to voltage.

A differential synchronous demodulation circuit is used to reduce the effects of other light sources and stray frequency inputs to the system. Because the IR and red signals are absorbed differently by body tissue, their received signal intensities are at different levels. Therefore, the IR and red signals must be demodulated and then amplified separately in order to compare them to each other. Demultiplexing is accomplished by means of two circuits that alternately select the IR and red signal. Selection of the circuits is controlled by two switches that are coordinated with the IR and red transmissions. A folter with a large tiem constant follows to smooth the signal and remove noise before amplification.

Differential Synchronous Demodulation Circuit

Before the current from the photodetector is converted to voltage, any high frequency noise is filtered by C40 and R17. The op-amp UIA is used in parallel with the current-to-voltage converter UID to cancel any DC voltage, effectively AC coupling the output of UID. The average value of the SpO_2 analog reference voltage (VREF) of UID, 5 V, is measured at pin 14 of test point 49.

U6D, a single-pole-single-throw (SPST) analog switch, is controlled by the same line that controls the on/off pulsing of the LEDs. When either of the LEDs are on (the line is low and the switch is closed) U35 is used as a non-inverting amplifier. When the LEDsa re both off, U35 is used as a non-inverting amplifier. When the LEDs are both off, U35 is used in an inverting amplifier. The signal at the output of amplifier U35 is then demultiplexed.

The CPU HSO lines SAMPRED and SAMPIR, which are both active low, control SPST analog switches U6A and U6B respectively. Switch U6A is closed to sample the red signal; switch U6B is closed to sample the IR signal. The sampling rate for both switches is 10 kHz. Switching is coordinated with the LED transmission so that the IR and red signals are each sampled twice per cycle; that is, once when the LED is off (signal inverted), and once when the LED is on (signal not inverted). The filtering circuit that follows has a long time constant, thereby acting as an averaging circuit.

If the instantaneous average photocurrent (DC offset) is excessive and UID cannot bring it to VREF, the PHOTOI line to the CPU (HSI0) is activated. This action is an indication of excess ambient light into the photosensor, or the occurrence of excess noise in the input circuit. It also serves as a warning to the instrument that the sensor signal may be contaminated and causes the software to send an error message. After about 3 seconds of continuous photocurrent signal, pulse search annunciation will begin. After about 10 seconds of continuous photocurrent signal, zeros will be displayed.

Signal Gain

The separated IR and red signals are amplified so that their DC values are within the range of the A/D converter. Because the received IR and red signals are typically at different current levels, the signal gain circuits provide independent amplification of each signal as needed. The gain in these circuits is adjusted by means of the PWM lines.

After the IR and red signals are amplified, they are filtered to improve the signal-to-noise ratio and clamped to a reference voltage to prevent the combined AC and DC signal from exceeding an acceptable input voltage from the A/D converter.

Variable Gain Circuits

The two variable gain circuits are functionally equivalent. The gain of each circuit is contingent upon the signals received level and is controlled to bring each signal to -3.5 V. Each circuit uses an amplifier and one switch in the trip SPDT analog multiplexing unit U2.

The gain in each of the circuits is accomplished by means of a feedback loop, which includes one of the SPDT switches in U2. The PWMs control whether the feedback loop is connected to ground or to the amplifier output. The feedback is then averaged by C33/R25 (red), and C34/R24 (IR). The higher the value of PWM2, the greater the IR gain; the higher the value of PWM1, the greater the red gain.

Filtering Circuits

These circuits consist of two cascaded second-order filters with a break point frequency of 10 Hz. Pairs of diodes (D1/D3 and D2/D4), which are located between VREF and ground at the positive inputs of the second amplifiers, maintain the voltage output within the range of the A/D converter.

AC Ranging

In order to achieve a specified level of oxygen saturation measurement and to still use a standard type combined CPU and A/D converter, the DC offset is subtracted from each signal. Because the DC portion of the signal can be on the order of one thousand times the AC modulation, 16 bits of A/D conversion would otherwise be required to accurately compare the IR and red modulations between the combined AC and DC signals. The DC offsets are subtracted by using an analog switch to set the mean signal value to the mean of the range of the A/D converter whenever necessary. The AC modulation is then super imposed upon that DC level. This is also known as AC ranging.

Each AC signal is subsequently amplified such that its peak-to-peak values span one-fifth of the range of the A/D converter. The amplified AC signals are then filtered to remove the residual effects of the PWM modulations and, finally, are input to the CPU. The combined AC and DC signals for both IR and red signals are separately input to the A/D converter.

Offset Subtraction Circuits

Voltage dividers R22 and R41 (red), and R31 and R5 (IR), which are located between VREF and ground, establish a baseline voltage of 2.75 V at the input of the unity gain amplifiers U7C (red) and U7D (IR).

Whenever SPST analog switches U11A and U11D are closed by HSO 0 (active low), the DC portions of the IR and red signals create a charge, which is stored on C29 and C89, respectively. These capacitors hold this charge even after the switches are opened and the resulting voltage is subtracted from the combined signal–leaving only the AC modulation output. This AC signal is superimposed on the baseline voltage output by U7C and U7D. The IRDC and REDDC are then filtered and input to the CPU, and can be measured at TP58 and TP54, respectively.

AC Variable Gain Control Circuits

The AC modulations are amplified by U7A (red) and U7B (IR) and superimposed on the baseline voltages present at the output of U7D (IR) and U7C (red). The amplification is handled by means of the SPDT analog multiplexing switch U3 within the feedback loop, which increases gain as PWM0 is increased. The IRAC and RECAC are then filtered and input to the CPU, and can be measured at TP55 and TP59, respectively.

Digital Circuitry

The digital hardware and related circuitry, which is illustrated in the following block diagram, includes the following subsystems:

- CPU – A 16-bit microcontroller that includes: a serial port, watchdog timer, A/D converter with an 8-input analog multiplexer, 3-pulse width modulators, and a high speed I/O subsystem.
- System Memory – External to the CPU and consists of an 8K x 8 static RAM and a 64K x 16 EPROM.
- Real-Time Clock (RTC) – The RTC keeps track of date and time, which is printed on each printout. The RTC is powered by a lithium battery designed to last up to 5 years before needing replacement.
- Audio Output – A piezolectric ceramic beeper is used for audio output.

- Display Control – A high-visibility display provides oxygen saturation and pulse rate values. An ambient light sensor responds to low light conditions and turns on the display backlight.

- User Controls – A measure button and a battery-check button. The measure button signals the power control circuit to switch on the power supply. Press and hold the battery-check button to display a percentage of useful life remaining in the batteries.

- Power Supply/Power Control Circuitry – The N-20P receives power from 4 "C" cell batteries. The power control circuitry discontinues power to the unit when the batteries are no longer reliable.

- Thermal Printer – Generates a hardcopy of oxygen saturation and pulse rate values. A sensor monitors ambient temperature and adjusts printer output to ensure consistent print quality.

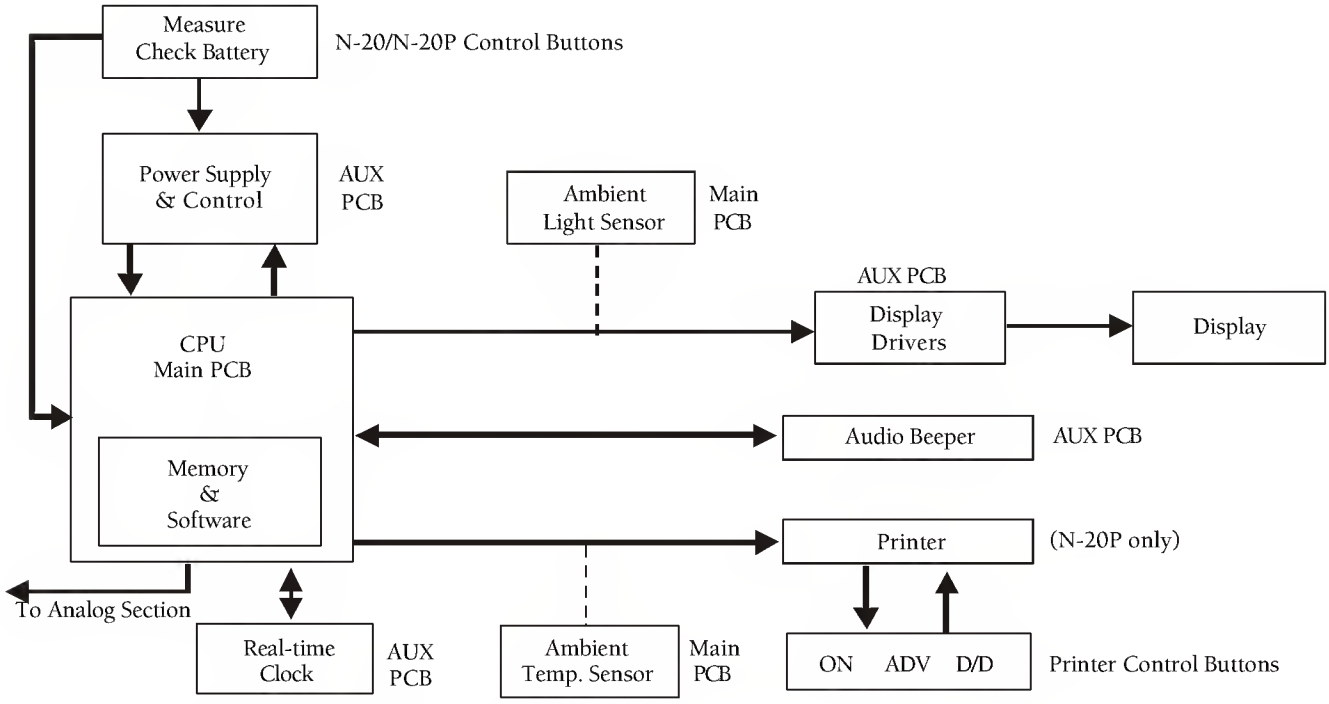

Figure 12.4 Digital Circuitry Block Diagram

CPU

The Intel 80C196KC CPU is a 16-bit microcontroller with built-in peripherals including: a serial port, watchdog timer, A/D converter with an 8-input analog multiplexer, three pulse width modulators, two 16-bit counter/timers, up to 48 I/O lines, and a high speed I/O subsystem.

The CPU is capable of running up to 16 MHz; but, it is run at 10 MHz for decreased power consumption. All unused inputs are tied to either Vcc or ground through resistors – this prevents unused inputs floating to any voltage and causing excess power drain. The READY input pin is tied high, thereby disabling wait-state generation; all bus accesses are zero-wait state. The EA pin is tied low to enable addressing of the external EPROM.

When the power supply is first switched on by the power control circuit, the reset generation circuit holds the CPU RESET pin low for at least 20 ms, then allows the internal pull-up resistor to bring it high; this assures a good CPU reset.

An internal watchdog timer is enabled and runs continuously. The watchdog timer provides a means of recovering from a software upset caused by ESD, EMI, etc. If the software does not clear the timer at least every 64K state-times (13.1 ms), the CPU will drive RESET low, resetting the entire unit. The reset output by the CPU is only 16 state-times long (3.2 µs). Q22 provides isolation from C65 so the CPU can drive a good reset to the display control circuit.

The CPU has the ability to dynamically switch the data bus width–based on the BUSWIDTH input pin. A low on BUSWIDTH tells the CPU to access memory only 8 bits at a time. When accessing the static RAM, BUSWIDTH is low, automatically reading the 8-bit wide RAM. Since BUSWIDTH is connected to the active low RAM enable line (RAMEN), all other memory and mapped I/O are read or written 16 bits at a time.

Eight analog inputs are measured by the CPU. Input from the SpO_2 analog section includes AC and DC signals for the oximeter sensor red and infrared channels, and the sensor calibration resistor RSENS. Light, temperature, and battery voltage are also measured.

The N-20P CPU is configured as follows:

- Decoded AD0 and BHE generates separate WR write strobes for the low and high bytes of a word. The signal WR (pin WRL) is the low-byte write strobe.
- A standard address latch enable (ALE) is generated and used.
- HSO pins 4 and 5 are configured as outputs. The HSO is used to generate stable timing control signals to the SpO_2 analog section, display, and printer.
- The timer-2 external control pins: T2CLK, T2RST, T2U-D, and T2CAPT are disabled via software and used as standard I/O.
- The HOLD, HLDA, and BREQ bus accessing is disabled via software and the pins are used as standard I/O.
- Pins HS10 and EXTINT are configured for interrupt input. The CPU receives 2 external interrupts (signals PR TACH and PHOTO1)
- RXD and TXD are configured as a standard asynchronous serial transmitter and receiver for the serial interface.
- PWM0, PWM1, and PWM2 pins are configured as pulse width modulator outputs. They are used to control gains within the SpO2 analog section.

Address Demultipleixing

U13 and U33 are transparent latches that latch the address portion of the AD bus data on the falling edge of ALE; the outputs are always enabled. The outputs of U13 and U33 are always the address portion of the AD bus.

Address Decoding

The CPU has a 64K byte address range of 0-FFFF. RAM, EPROM, and I/O ports share this space. The address decoding circuit splits up this space and output enable lines to the RAM, EPROM, and I/O ports.

U30A generates the static RAMs active low enable signal, RAMEN. When address lines A13, A14, A15 are all high, U30As output goes low, enabling the RAM. This occurs for the 8K address range of E000-FFFF.

U30B and U28 are used to generate the input port and output port active low enable signals EXINEN and EXOUTEN. When address lines A15, A14, A11, and A10 are high, and A13 is low, U28 becomes enabled. With U28 enabled, one of the 8 outputs is set low. The output to go low is selected by pins A, B and C. They form a 3-bit binary number with pin C being the most significant bit. So when address line A12 is high, WR active (low) and RD inactive (high), a binary 5 is produced on pins A, B, and C, forcing output Y5 (EXOUTEN) low. This enables the output port for writing. When address line A12 is high, WR inactive and RD active, a binary 3 is produced on pins A, B, and C, forcing output Y3 (EXINEN) low. Note that in both previous conditions, A15, A14, A12, A11, and A10 are high and A13 is low.

The input port and the output port both share the same 1K byte address space of DC00-DFFF. When data are written to the address, the output port enable signal EXOUTEN is activated. But when data are read from the same address, EXINEN is activated. Because the CPU is configured to use a 16-bit bus, except for RAM, any even address in the DC00-DFF range could be used for external port access. In other words, reading or writing address DC00, DC02, DC04, etc., will all produce the same results. Due to the CPU configuration, the write strobe WR (WRL pin), is only active for low-byte writes; therefore, both bytes of the external output port must be written to at the same time. The upper byte of the output port cannot be written to alone, no write strobe and, therefore, no EXOUTEN signal will be generated.

U30C generates the EPROMs active low enable signal, ROMEN. The active low signals RAMEN and EXINEN are basically used as EPROM disable signals. When RAMEN or EXINEN or test point TP71 are low, the output of U30C, ROMEN, is forced high, disabling the ROM. Therefore, the EPROM is disabled for the range DC00-FFFF and enabled for the 55K byte address range of 0h-DBFF. TP71 is used during board testing to disable the EPROM.

CPU Memory

The memory system external to the CPU consists of an 8K x 8 static RAM(U14) and a 64K x 16 EPROM (U15). The EPROM is 16-bits wide to enhance CPU performance. Because RAM is infrequently accessed, it is only 8 bits wide.

U14 is a standard 8K x 8 static RAM. Test point TP 43 is used during testing to disable the output.

The program that the CPU runs is stored in U15. U15 is a 16-bit wide output, one-time programmable (OTP) EPROM. During 16-bit wide bus accesses, the CPU uses address line A0 for low/high byte selection; and is not used as a normal address line. The CPU can only address 64K x 8 bytes or 32K x 16 bytes. Pin A15 of U15 is tied low, always selecting the lower half of the EPROM. Signal ROMEN is then used to enable the EPROM for the proper memory area.

Input Port

U16 is the input port external to the CPU. The logic levels on the inputs (pins D1-D8) are output to the CPU via the AD bus while EXINEN is strobed low. All of the user control buttons are input via U16. Also, the battery type is sensed via U16; a high on signal BATTYPE signifies to the CPU that rechargeable batteries are being used. If the optional printer head is in the home position. PR HOME will be a logic high.

Pin D8 (RTC_IO) and an output bit of the external output port arc connected. They work as a pair to create a bidirectional bit for communicating with the RTC (see"Real-Time Clock and Non-Volatile Memory").

Output Port

The output port external to the CPU consists of 2 octal D latches, U18 and U17; they function as a single 16-bit output port. U18 is the lower byte (LSB) and U17 is the upper byte (MSB). The output of U18 is always enabled. The output bits of U18 control: audio output, optional printer, RTC, and display.

The signal PR STROBE controls U17s output drivers. Under normal operation, the outputs are tristated and resistors R148-R154 pull the outputs low. PR STROBE is driven low to turn on the output drivers of U17. Signals PR DOT0-PR_DOT6 (pins Q1-Q7) drive the 7 print dots of the optional printer. PR STROBE pulses all 7 of the dot lines for a specific time period (see also "Printer Interface"). When the CPU is first powered on, PR STROBE is in a tristate condition. R123 assures that U17 does not accidentally turn on the printer head dots until required to. Pin Q8 (RTC_IO) and an input bit of the external input port are connected. They work as a pair to create a bidirectional bit for communicating with the RTC (see also "Real-Time Clock and Non-Volatile Memory").

Both bytes of external output port (i.e., U18 and U17) must be written to at the same time. The upper byte of the output port (U17) cannot be written to independently (see also "Address Decoding").

Real-Time Clock (RTC) and Non-Volatile Memory

The RTC has two functions: (1) it provides non-volatile memory that is used to remember whether the printer should be enabled at power on, and (2) to keep track of time and date for the N-20P printer. The N-20 does not require or use the RTC; it is disabled via software.

The RTC chip U29 uses a 3-wire synchronous serial interface to communicate with the CPU. The CPU brings signal RTC_RST high to activate communication with the RTC. RTC CLK clocks data into and out of the RTC chip. RTC 10 is the bidirectional communication data bit. The CPU drives RTC 10 when writing data and commands to the RTC. The CPU tristates RTC 10 and then reads data back on it from the RTC.

Crystal Y1 provides an accurate 32.768 KHz clock input whenever the time keeping circuitry of U29 is activated. The CPU only enables the timekeeping function when an optional printer is installed. If no printer is installed, the RTC clock is only used during diagnostic testing to verify the CPU clock timing.

The lithium battery BT1 and diodes CR23 provide the power switch over and constant power needed to keep the time and RAM data while the unit is not in use. Whenever the unit is powered on, Vcc is at 5 V and U29 is powered via CR22. CR23 is reverse biased because BT1 at 3 V is at a lower potential than Vcc. Whenever the unit is powered off, the potential between Vcc and switched ground is 0 V, CR23 is forward biased, and U29 is powered by BT1. CR22 is reverse biased, isolating BT1 from Vcc. This circuit design allows BT1 life of up to 5 years, typical, without the unit being powered on.

U29 holds 24 bytes of RAM, which is used for non-volatile storage of CPU data.

Audio Output

BZ1, a piezo ceramic sounder, is the audio output device. Due to its low drive current of 2 mA maximum, no drive circuitry is needed and is driven directly from the external output port. It is differentially driven with 2 square waves 180 degrees out of phase. The drive frequency is approximately 1480 Hz or 740 Hz and is generated by the CPU. BZ1 is differentially driven to obtain maximum audible volume.

Display Control Circuitry

The Taliq display is controlled by the display control circuitry. A photosensor measures ambient light and automatically switches on the electroluminescent display backlight during low light conditions. The display control circuitry is divided into the following subsections.

- Control Conditioning Circuit (main PCB) – The control conditioning circuit processes signals generated by the CPU to produce timing signals for the display drivers.
- Display Driver ICs (auxiliary PCB) – Each of the two display driver ICs have 32 high-voltage outputs that enable individual segments of the display to be turned on or off.
- High Voltage Control Circuit (auxiliary PCB) – The high voltage control circuit allows the CPU to switch on or off the display's high voltage input.

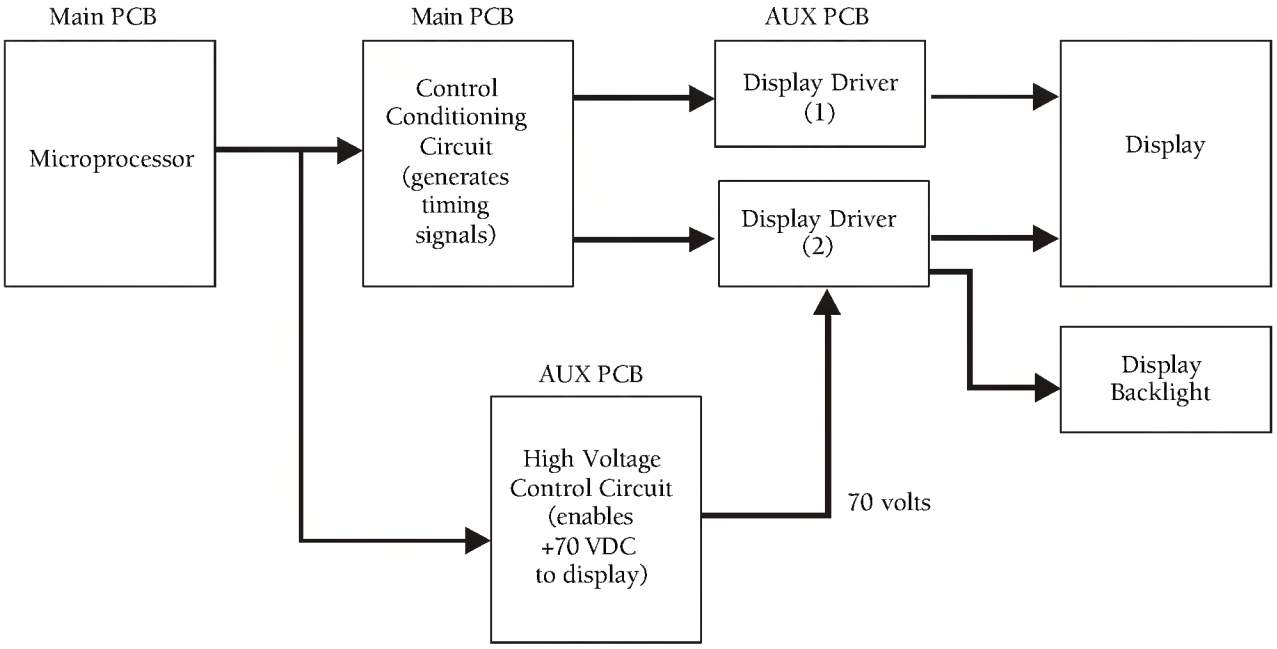

Figure 12.5 Display Control Block Diagram

Control Conditioning Circuit

The CPU generates a 400 µs low pulse rate train at a 160 Hz rate on signal DISP PHASE. Half of U34 takes DISP PHASE as an input and creates DISP POL as an 80 Hz 50% duty cycle square wave. A CPU reset initializes DISP POL low when any CPU reset occurs so the software knows the initial state. The other half of U34 is used to synchronize the rising edge of the DISP DL iwht the rising edge of DISP POL. The CPU brings DISP LATCH signal high before the rising edge of DISP PHASE; this allows the high to be clocked out to DISP DL on the rising edge of DISP PHASE. About 100 µs after the rising edge of DISP PHASE, the CPU brings IDSP LATCH low, asynchronously resetting DISP DL low.

Display Driver Control Circuits

U19 and U20 are the display segment driver chips. Each chip has 32 high-voltage outputs and a display common marked BP (backplane). The display data are input to U19 and U20 by the CPU via a serial shift register input. U19 and U20 are daisy-chained together forming a 64-bit serial shift register. Display data are loaded and shifted down via the DISP DATA and DISP CLK signals When all 64 bits of the shift register are loaded, a high pulse on DISP DL updates the display, all 64 bits at the same time. The display is clocked with an 80 Hz 50% duty cycle waveform by signal DISP POL. The display cannot be driven by DC voltages or display damage will result. Display segments are illuminated by creating a 180-degree phase shift between the segment pin and the BP common pin. Segments are left dark by making the waveform on the segment pin be in phase with the BP pin. The display has an electroluminescent (EL) backlight, and is driven the same as the display segments. Connectors JP2, JP3, and JP5 connect the display and EL backlight to the drive electronics.

High Voltage Control Circuit

The cold switch circuit performs two basic functions: (1) it allows the CPU to enable and disable the display high voltage VDISP, and (2) it slows the edge slew rate of the segment drivers as it switches the high voltage. When the signal DISP PHASE is low, Q14 is disabled, pulling VDISP low. Whenever the CPU is powered on, DISP PHASE is tristated. The base emitter junction of Q12 pulls DISP PHASE low, disabling the high voltage. This assures that the high voltage is only enabled to the display when controlled by the CPU.

The Taliq display is similar to an LCD in that the load of a segment is mainly capacitive. A cold switch circuit provides a current-limited 70 V to VDISP. R93, R95, Q21 and Q14 do the on/off switching and current limiting. As the driver chips' output waveforms and DISP PHASE change states, the capacitive output current is integrated into the display capacitive loads, causing a highly linear rising and falling voltage ramp on VDISP. Because the high voltage to the drive chips (VDISP) is ramped, the outputs of the driver chips U19 and U20 are also ramped at the same controlled rate. This design is used to reduce current spikes on the 70 V power supply, and, in addition, reduces the EMI generated by the display due to the lower slew rates of the high voltage switching signals.

Standard User Controls

The standard user controls consist of two momentary push-button switches (measure and check-battery). The measure button is an elastomeric contact switch, and the check-battery button is a mechanical momentary switch.

The CPU input lines BAT BTN an GO BTN are normally pulled to the high state by R71 and R78. Whenever a button is depressed, the CPU input line is pulled low through R74 and R80. The switch contacts are debounced with C64 and C66. L11, L12, C126, and C123 provide a current path for ESD protection.

In addition to being read by the CPU, the measure button also activates the power supply via the power control circuit. Note that the measure button has circuitry on both the main PCB as well as the auxiliary PCB.

Power Supply/Power Control Circuitry

Power supply circuitry is located on the auxiliary PCB and consist of the following subsections:

- Batteries – Four 1.5 V alkaline "C" size batteries provide 4-6 VDC power.

- Power control circuitry – Power control circuitry is connected to the batteries. It senses any press of the measure button and switches on the power supplies. Reverse current limiting protects the N-20P from damage if batteries are inserted incorrectly.

- Power shut-off circuit – This circuit controls power to all circuits except the power control circuit. In addition, a fuse protects the power supply from excessive current draw. The power supply is also protected against electrostatic discharge and electromagnetic interference.

- Power supply circuits consist of the following power supplies:

  Regulated power supply: Power supplied by the batteries is regulated at 5 VDC. This supply is used by all of the digital circuitry and some of the SpO_2 analog circuitry.

  Unregulated power supplies: 5 VDC is connected by a switched capacitor network into unregulated power supplies of -5 VDC, 10 VDC, and 12 VDC, all of which are used in the SpO_2 analog circuits.

  High voltage power supply: A voltage regulator/doubler converts battery voltage to 70 VDC; this increase in voltage is needed by the display drivers as well as the display backlight.

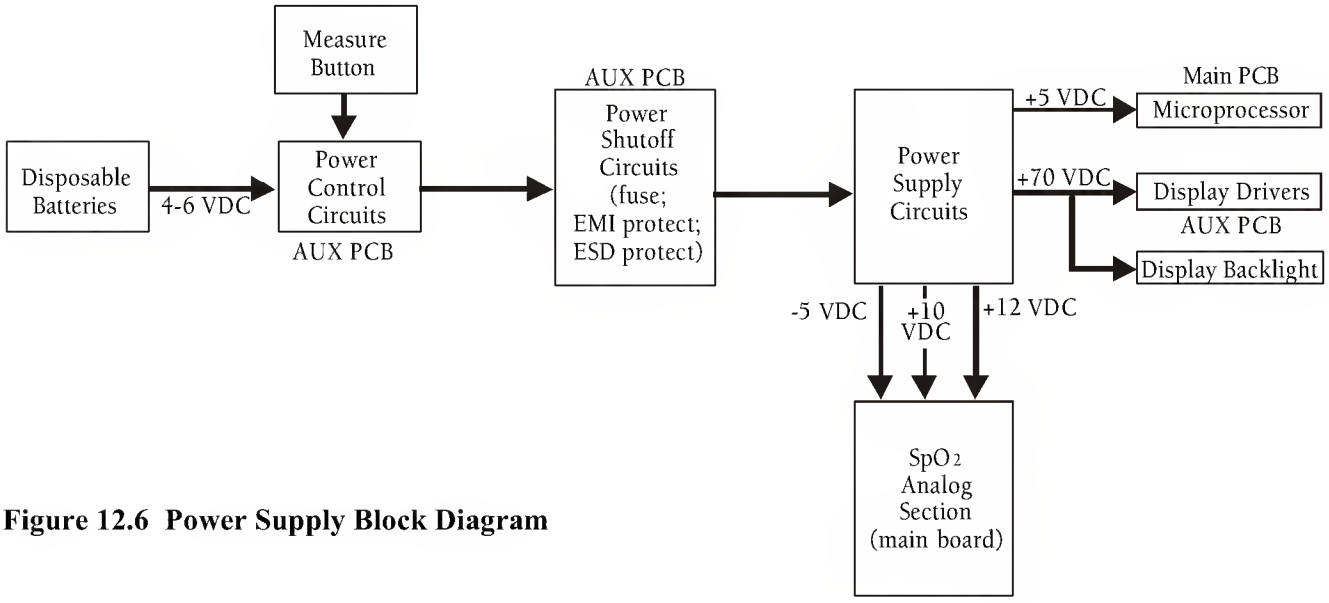

Figure 12.6 Power Supply Block Diagram

Power Control Circuitry

The power control circuit consists of U21 and its associated components. U21 is a D flip/flop with asynchronous preset and clear; only the preset and clear are used.

Power is applied to U21 via CR11 whenever batteries are installed. CR11 provides protection for U21 if the batteries are installed with reverse polarity. This error condition will reverse bias CR11, thereby disabling current flow to U21.

The much larger RC time constant of R110, C67 compared to R78, C66 guarantees that the unit will not be accidentally powered on when batteries are first installed.

Whenever the measure button is pressed, a low on GO SW sets the output signal PWR ON high. This condition connects switched and battery grounds, enables the power supplies, and switches on the unit. Whenever the CPU determines that the power should be switched off, it forces PWR DOWN low. This action clears output PWR ON to a logic low, disconnecting ground, and switching off the power supplies (see also "Power Supply").

R79 and R81 provide current limit protection to U21 inputs. They also limit the current that will flow through U21 inputs to the CPU when the batteries are installed backwards. In the reverse battery error condition, massive current can flow from the inputs of U21 through the input protection diodes and/or substrate inside the CPUs integrated circuit. These resistors limit that current path to safe levels.

Power Shut-off Circuit

Fuse F1 protects the unit from excessive current draw. CR24 protects against large voltage transients caused by ESD, EMI, etc.

Q15 is a dual-channel FET; the drain of Q15 part 2 (pin D2) is connected to battery ground; the gate (G2) is connected to battery plus; and R155 applies a bias to the source (S2) so it will switch on when a positive voltage is applied to G2. When batteries are correctly installed, Q15 part 2 is switched on and conducts. If batteries are installed backward, Q15 part 2 switches off and disables current flow. This protects the units power supply circuitry from an accidental reversal of battery potential.

Q15 part 1 controls the power supplies. When a logic high is placed on the gate (pin G1) signal PWR ON battery ground is connected to the circuit and switched to ground via Q15 parts 1 and 2. When the power control circuitry pulls PWR ON low, switched ground switches to a high impedance state. This action switches off the power supply, and therefore the unit, except for the power control circuit.

Vcc Power Supply

The Vcc power supply is a switched inductor voltage regulator operating in boost mode (U22). The power input is provided by the batteries (VBAT). NFET (Q17) operates as a linear post regulator. The I M resistor (R77) operates as a static bleed device across the switched regulator when the regulator is switched down. The regulated output is Vcc (5 V ± 5%).

Raw Power Supplies

The input to the raw power supplies is VCC, which is a switched-capacitor voltage converter operating in separate multiply and invert modes in conjunction with supporting circuitry. U23 inverts Vcc and outputs raw -5 V. Raw 10 V is derived by voltage doubling Vcc with CR14, CR19, CR20, and CR78. Raw 12 V is derived by voltage tripling Vcc with CR15, Q8, Q9, C96, C81, R119, and R120.

The raw power supplies are used as bias supplies for the SpO_2 analog section and are not tightly regulated. The normal operating range of the raw power supplies are:

raw -5.0 V = -6.0 V to -4.0 V
raw 10.0 V = 7.5 V to 11.0 V
raw 12.0 V = 12.0 V to 15.0 V

High Voltage Supply

The input power for the high voltage supply is provided by the batteries (VBAT). The high voltage supply is a switched-inductor voltage regulator (U26) that operates in conjunction with a capacitive voltage doubler to output 72 VDC + 5%. To protect against a runaway voltage condition, CR25 clamps U26's output to a safe level.

Serial Interface

The serial interface is only used for test purposes, and is not at the RS-232 level, neither is it electrically isolated and, therefore, cannot be used when the unit is connected to a patient. The serial data port JP1 is a TTL level serial interface. RXD and TXD are configured as a standard asynchronous serial transmitter and receiver at 19.2 Kbaud with 1 stop bit, 8 data bits, and no parity. The serial interface can operate in full duplex mode.

Ferrite beads L6, L7, and capacitors C120, C121 provide ESD protection for the CPU. If no serial port is connected, R128 pulls RXD input low; this action prevents an unused input from floating.

Analog Reference Voltage

U32 provides an accurate, regulated voltage that is used as the reference voltage for the A/D inside the CPU. Filtering is provided by C6, C12, and R124. The voltage output VREF is 5 V.

Ambient Light

Diode D8 is a photodiode that is used to measure ambient light. Q8, R68, and R136 provide current gain for D8s photocurrent. The amplified photocurrent flowing through R136 creates a voltage drop, which is measured by the CPU. The CPU continually monitors the light source output at AMB LIGHT (TP72). Under low ambient light conditions, the CPU automatically switches on the display backlight.

Ambient Temperature

U5 is a precision-temperature sensor. It outputs (PR TEMP) a voltage proportional to the ambient temperature, which is 10 mV per degree centigrade. For example, at a room temperature of 25°C, the U5 output would be 250 mV. U5 is used whenever an optional printer is installed, because the printer is a thermal printer, ambient temperature must be compensated for.

Battery Voltage

The analog input voltage range of the CPU is 0-5 VDC. Because the battery voltage may be as high as 6.2 V, R69 and R70 form a voltage divider to decrease the measured battery voltage to a usable level. The gain is 0.75; thus, if the battery voltage was 6 V, then the voltage of BAT VOLT would be 6 x 0.75 which equals 4.5 V.

The software has the ability to determine when battery power is too low. If the software determines that the battery voltage is too low to provide accurate information, the software generates an audible signal and automatically switches the unit off. If an optional printer is installed, the battery voltage data are used to compensate for battery voltage changes that can affect printout quality.

Battery Type

The unit can operate with either disposable or rechargeable batteries. Battery type input is digital; a high input informs the CPU that rechargeable batteries are in use. If rechargeable batteries are used, the battery and the VRECHARGE terminals are mechanically connected. This applies the battery voltage to VRECHARGE, pulling BAT TYPE high. R100 and CR27 are a current-limiting resistor and a voltage-clamping diode that are used to protect the input port from excessive battery voltage. If disposable batteries are used, VRECHARGE is electrically isolated, which allows R101 to pull BAT TYPE input low.

The nominal voltages and voltage discharged curves are significantly different between rechargeable and disposable batteries. In order for the CPU to predict how much "battery life" remains, the nominal voltage and discharge curves must be known; the BAT TYPE signal provides that information.

Printer Control

Printer circuitry is divided into two subsections: the printer interface and the printer flex circuit. Printer interface circuitry is present on both models, but is disabled by software in the N-20.

- Printer interface circuit (auxiliary PCB) – This circuit detects the presence of the flex circuit, and supplies power to the printer heads and paper advance motor. Electrical noise generated by the printer motor is filtered. The circuitry is protected from excessive battery currents by a fuse.

- Printer flex circuit (N-20P only) – The printer flex circuit is added when the printer is present. The printer generates a timing signal that is read by the CPU and sent to the flex circuit. This circuit signals the CPU that a printer is present by connecting one CPU input to ground. Power and power control signals from the auxiliary PCB generate an output load for a resistor array; heat from this process produces a dot matrix pattern on thermal paper.

User control is provided by momentary push buttons: ON (on/off), ADV (advance), and D/D (day/date). ON enables or disables the printer, ADV controls the advance of printer paper, and D/D sets date, time, and other clock parameters.

When a low battery voltage condition is present, the N-20P adjusts power to the printer's head; however, a weak battery voltage condition causes the printer to shut off, thereby allowing the N-20P to continue to display oxygen saturation and pulse rate readings until the batteries are exhausted. An ambient temperature sensor adjusts printout quality to compensate for environmental conditions.

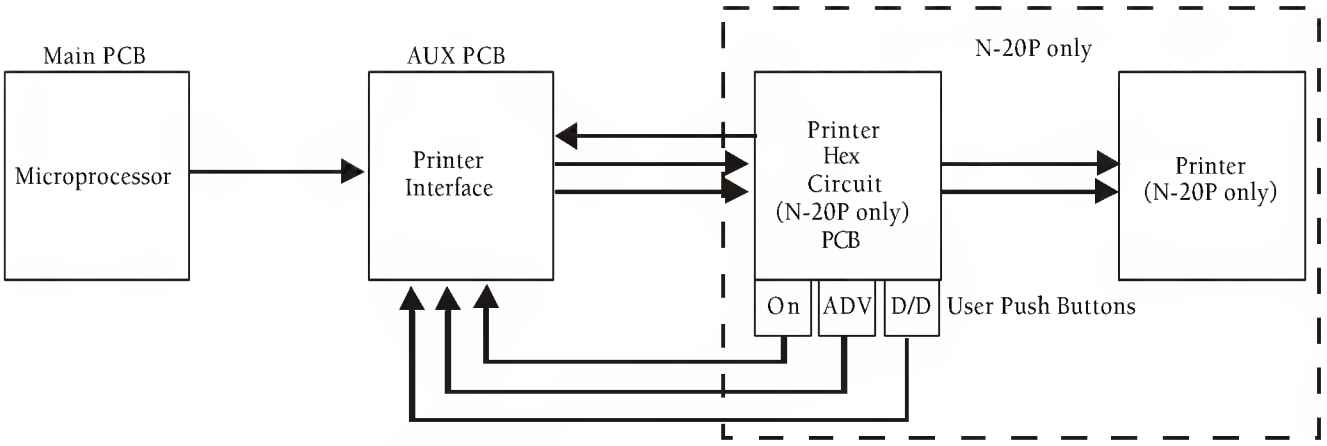

Figure 12.7 Printer Control Block Diagram

Printer Interface Circuit

The following is a description of the printer interface circuitry found on all N-20P auxiliary PCBs.

The CPU reads the PR PRESENT signal to determine if a printer is installed. With PR PRESENT left floating, it is pulled high by the weak pull-up resistor inside the CPU. If a printer is installed, PR PRESENT is connected to switched ground, which causes a low input to the CPU. The optional printer circuit is protected from excessive battery currents by fuse F2. CR28 is used to block noise generated by the printer motor being injected onto the batteries.

The N-20P printer is a 16-character-wide thermal dot matrix printer, which generates a CPU interrupt for every dot column. The thermal energy given to the print head is controlled by the pulse width of the active high signals PR DOTx. In order to provide consistent print quality, the ambient temperature, print drive voltage, and print head resistance must be measured and accounted for.

Inside the print head are seven resistors that heat up when power is applied, and in turn create dark dots on the thermal paper. One lead of the print-head resistors is connected to the printer supply voltage VPRN; the other lead is connected to the driver chip (see "Optional Printer Flex Circuit with User Controls"). One of the print dot resistor leads (DOT4) is also fed back to the printer interface circuitry. The DOT4 signal is a print dot resistor with a range of 11-16 ohms, which is connected to VPRN.

The print head resistance is measured by U36. A two-level resistor bridge is formed by R143, R144, R145, R146, and head resistor DOT4. The resistor bridge is switched on when PR MEAS is pulled high, pulling TP77 low and biasing the resistor bridge. The logic outputs of PR HEAD1 and PR HEAD2 are read in by the CPU to determine which of the three head resistance categories this particular head is. R156 ensures that Q20 does not switch on when the batteries are installed backward. Due to the large current draw of the resistor bridge and the fact that the head resistance does not change significantly over time, the head resistance is only measured once at every power on.

The CPU starts the printer motor running by setting PR MOTOR high. A single motor drives both the print head and paper advance mechanisms. The printer provides a printer timing generator (TG) signal, which is an AC waveform of about 4 Vpp. Q19, R106, R142, and CR29 convert the AC waveform to a CMOS level square wave; this signal (PR TACH) is then used as a CPU interrupt line. An interrupt routine services the printer, thereby producing the required dot patterns to create the characters. C127 is used to filter noise.

The position of the print head is sensed by the signal PR HOME. Whenever the print head is not in the home position, a switch in the printer closes, shorting PR HOME to switched ground. Whenever the print head is in the home position, the switch opens, allowing R118 to pull PR HOME high.

The print head dot pattern and pulse width are controlled by the CPU. The proper printer dot values are loaded into the output port, then the proper pulse width is loaded into the CPU CAM for PR STROBE. The signal PR STROBE enables the outputs for the specified pulse width. When the PR DOTX lines are high, a dot will be printed.

Printer Flex Circuit and User Controls

The thermal printer is plugged in via connectors JP10 and JP11. The PR PRESENT signal is connected to switched ground to tell the CPU that a printer is installed. U1 is a Darlington pair driver chip that is used to drive the printer dots and motor. When an input is high, the output is shorted to the ground, driving the output load.

Constant power (VPRN) and a power control line (PWR ON) are provided by the auxiliary PCB. Q1 is used as a power control FET. Both halves are used in parallel to reduce the on resistance. When PWR ON is high, the sources (S1, S2) short to the drains (D1, D2), connecting ground to U1 and C3. PWR ON also controls the regulated power supplies; thus, Q1 and the power supplies are both enabled and disabled at the same time.

The large bulk capacitor C3 is required due to the large current spikes that are required by the printer and the large internal series resistance of disposable batteries. Bulk capacitance is required to lessen the battery voltage drop by the current spikes.

The N-20P has three additional user-control buttons. L8, L9, L10, C120, C121, and C122 provide ESD protection. R103, R104, and R105 provide pull-ups when the user buttons are open. These pull up resistors are in the printer interface circuit to ensure that the buttons (ON, ADV, and D/D) are never left floating, regardless of whether an optional printer flex circuit is installed or not.

The optional user controls consist of three momentary push button elastometric contact switches. Pull up resistors are provided by the printer interface circuitry. R1, R2, and R3 help protect the input port by providing some current-limiting capability. C4, C5, and C6 debounce the switch contacts.

12.3 Calibration Verification for N-20P

CAUTION: Adhere to all testing instructions; failure to do so may damage the N-20P.

Overview

The N-20P is powered by alkaline batteries. The N-20P design includes built-in electrical insulation, no ground resistance or electromagnetic leakage testing is required. In addition, the N-20P required no calibration.

Required Tools and Equipment

The following tools and equipment are needed to perform test procedures.

- SRC-1 pulse oximetry tester
- Variable DC power supply; 1 amp supply, voltage range 0-6 VDC

Power-On Self Test (POST)

When an N-20P is switched on, a sequence of diagnostic tests are run that examine the instruments electronics and display functions. This power-up self-test consists of the following events:

Immediately after power is switched on, the instrument simultaneously:
- Displays the number "8" in all six Oxygen Saturation and Pulse Rate display field segments;
- Illuminates all 14 pulse rate amplitude indicator segments; and
- Illuminates the Pulse Search and Low Battery indicators.

During the next few seconds, the instrument:
- Switches off the display backlight;
- Displays three digits in the Oxygen Saturation display field representing the software version (for example, 123 is software version 1.2.3).
- Displays the printer status in the display fields; that is, either "Pr On" or "Pr OFF".

If a sensor is attached to the instrument, a zero ("0") appears in first position of the display fields, and the Pulse Search indicator flashes; if no sensor is attached to the instrument, horizontal dashes appear in all six Oxygen Saturation and Pulse Rate display fields, and the Pulse Search indicator flashes.

After approximately 1 minute:
- A short beep occurs and the instrument automatically switches off.

If at any time during the test sequence "Err" followed by a code number is displayed, make note of the error code and refer to error code descriptions in this manual.

Low Battery Test

The N-20P CPU monitors the battery voltage level and alerts the user via the Low Battery indicator when voltage is getting low. To test the proper function of the Low Battery indicator, connect the N-20P to an external, variable DC power supply.

Battery voltage levels below are accurate; however, slight variations may exist due to differences between batteries of different manufacturers. To that point, the N-20P operates normally at voltages above 4.0 VDC.

When the battery voltage drops below 4.5-3.8 VDC, the Low Battery indicator is lit, and the two lowest segments of the battery level meter are lit when the battery check button is pressed. When the voltage level drops below 4 VDC, the N-20P continues to display Oxygen Saturation and Pulse Rate values, but the printer no longer operates; otherwise, the N-20P operates normally.

Battery voltage levels below 4.0-3.4 VDC cause the Low Battery indicator to begin flashing. When the battery check button is pressed only the lowest segment of the Low Battery indicator will illuminate.

When the battery voltage level drops below 4.0-3.4 VDC, the N-20P turns itself off.

CAUTION: If a sensor is attached, remove it prior to running the following test.

1. Switch off the N-20P; open the battery door and remove the batteries.

2. Set the power supply's voltage to 5 VDC, and connect the supply to the battery clips of the N-20P – *ensure that polarity is correct.*

3. Switch on the N-20P; verify complete POST (the N-20P should operate normally).

4. Decrease the power supply voltage to 4.0 VDC or slightly below. Then, press the battery check button; within 15 seconds, the Low Battery indicator should illuminate and the lowest two segments of the battery level meter should illuminate; the sensor LEDs should remain lit; and, printer operation should cease.

5. Decrease the power supply voltage to 3.45 VDC or slightly below. Then, press the battery check button; within 15 seconds, the Low Battery indicator should begin to flash and only the lowest segment of the battery level meter should illuminate.

6. Decrease the power supply voltage to below 3.2 VDC. Within 15 seconds, the N-20P should turn itself off. Pressing the measure button should not turn the unit back on.

7. End Low Battery test.

Performance Testing

The N-20P will operate in conjunction with the NELLCOR pulse oximetry tester, model DRC-1, to test instrument performance. The SRC-1 plugs into the DB-9 sensor connector and uses the instrument's power supply and diagnostic software to test the display, the accuracy of the oximetry values and the operation of the instrument. Nellcor recommends routine performance testing at 1-year intervals. Refer to the SRC-1 operator's manual for details on performance testing with the SRC-1.

Other tests, which are outlined below, include the display backlight test, the low battery test, and the thermal printer test.

Backlight Test

The electroluminescent backlight illuminates the display in three sections: (1) the main section, ie., the Oxygen Saturation and Pulse Rate display fields, and the 14-segment pulse rate amplitude indicator; (2) the Low Battery indicator and (3) Pulse Search indicators each have their own backlight. Each backlight flashes once during POST.

The ambient light is located underneath a small circular window in the top right corner of the N-20P display. Under low light conditions, the main section backlight is switched on. If a Low Battery and Pulse Search indicator is lit, its backlight is also lit.

To test for proper operation of the display backlight, observe the N-20P in a darkened room. If any backlight section is not working correctly, contact Nellcor's Technical Services Department or Nellcor's local representative for assistance.

Printer Test

The SRC-1 can be used to test the operation of the N-20P printer and the printer's user-control buttons. When an SRC-1 is plugged into the DB-9 connector, the N20P does not respond to button presses during POST; however, it does acknowledge any button press with an immediate beep and the following play codes:

Button Press	Display
measure	gO
battery check	bAt
ON	On
ADV	Ad
D/D	dd
combinations	Err

1. Press the measure button: "gO" appears in the Oxygen Saturation display.

2. Press the battery-check button: "bAt" appears in the Oxygen Saturation display.

3. Press the printer ON~ button "On" appears in the Oxygen Saturation display.

A printer test pattern prints out; the following is an approximate example of the test pattern:

N-20P PRINT TEST
00-00-00 00:00
ABCDEFGHIJKLMNOP
QRSTUVWXYZp2%.*-.
0123456789:#',
()!<>?V≈√~
vvvvvvvv
= = = = = = = =

Examine the test pattern to verify that all dots print with a uniform darkness. Overall printout darkness can be adjusted. If printout darkness is either irregular or dots are missing, contact Nellcor's Technical Services Department or Nellcor's local representative for assistance.

4. Press the printer ADV button: "Ad" appears in the Oxygen Saturation display. Paper advances one line for each button press.

5. Press the printer D/D button: "dd" appears in the Oxygen Saturation display.

6. End SRC-1 printer test

12.4 Troubleshooting

WARNING: Disassembly of the N-20P can expose service personnel to potentially hazardous voltages. For protection of service personnel and patients, the procedures must be performed as described in this section. Repair and testing must only be performed by qualified service personnel. Improper repair and/or adjustment may compromise patient safety or the accuracy of the instrument.

Required Equipment/Tools

- Screwdriver, Phillips
- Screwdriver, small flathead
- Pliers, long nose
- Soldering iron, low-power

N-20P Disassembly Procedure

Whenever repair or disassembly is required, always wear a ground strap connected to active ground. Before any disassembly or service procedure, switch instrument power off.

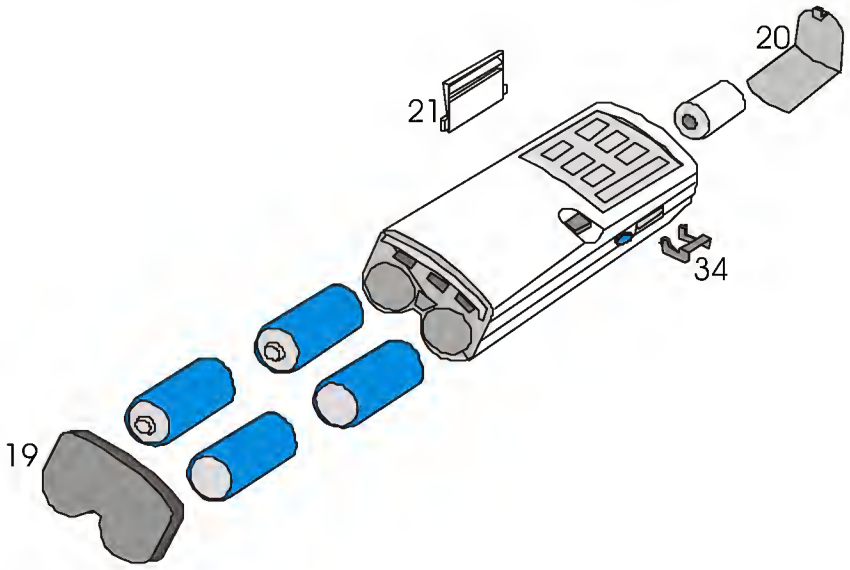

Figure 12.8 Sensor Lock, and Printer, Paper, and Battery Access Doors

1. Remove the battery door (19) and batteries.
2. Remove the sensor lock (34) by lightly pressing in on its ears and pulling out from the sensor shroud.
3. Remove the paper door (20) and paper roll, and the printer door (21).

Removing the Covers

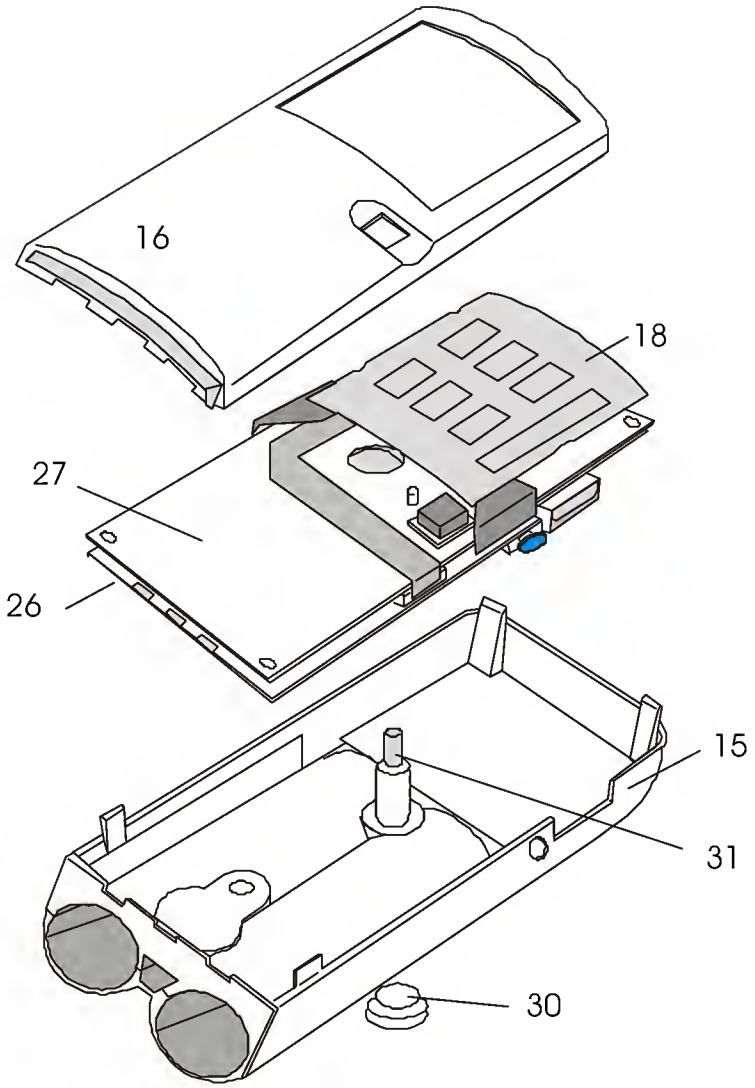

Figure 12.9 N-20P Covers with the PCB and Display Assembly

1. Remove screw cap (3), and loosen the captive screw (31) which secures the rear battery cover (15).

2. Separate the front cover (16) from the rear cover by wedging a thin flathead screw driver between the covers at the base of the instrument and slowly prying them apart.

> **NOTE**: The covers are hinged at the top end in a different way; do not attempt to separate the covers using this technique at the top of the instrument. Once the covers are separated at the bottom end, lift away the bottom end of the front cover first, allowing the tabs at the top end to act as a hinge.

Removing the PCBs and Display Assembly

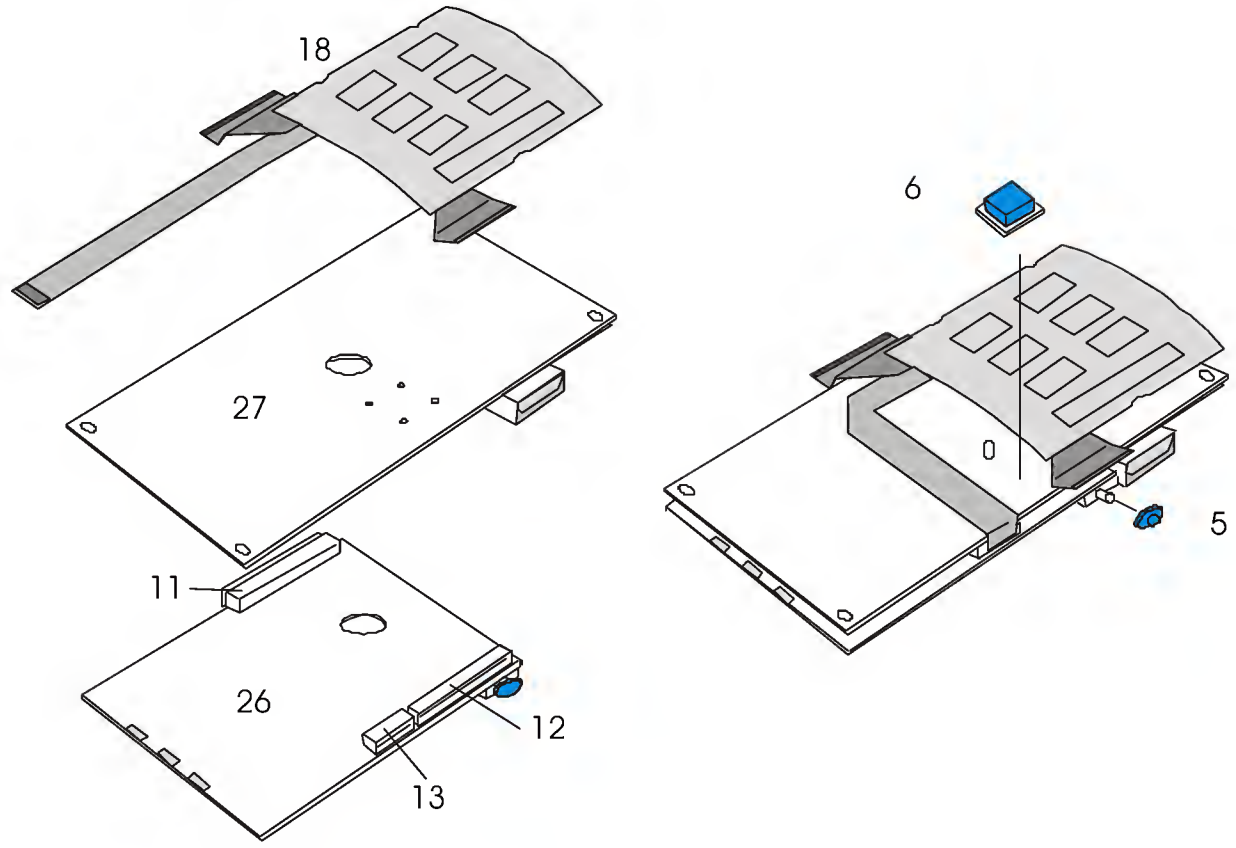

Figure 12.10 Main, Auxiliary, and Display PCB Assembly

1. Remove the measure button (6) from the main PCB.

2. Remove the entire PCB/Taliq display assembly from the rear battery cover by tilting opposite the battery check button (5).

3. Release connectors (11, 12, and 13) on the auxiliary PCB (26) and remove the three flex display circuits.

4. Separate the auxiliary PCB from the main PCB (27) by pulling the PCB headers apart at the base.

5. Remove the display assembly (18) from the main PCB by unsoldering the four tabs that are physically bent around the main PCB. These tabs are bent to ensure contact with the ground plane of the main PCB.

6. Using a long nose plier, remove the metal shroud by untwisting the four tabs (see Detail A and B).

N-20P Disassembly Procedure

1. Remove the paper door (20) and any printer paper by firmly grasping the paper roll, and pulling the roll outward from the printer.

2. See "Disassembly procedure for removal of covers, PCBs, and the display assembly".

Disassembling the Printer/Flex Circuit Assembly

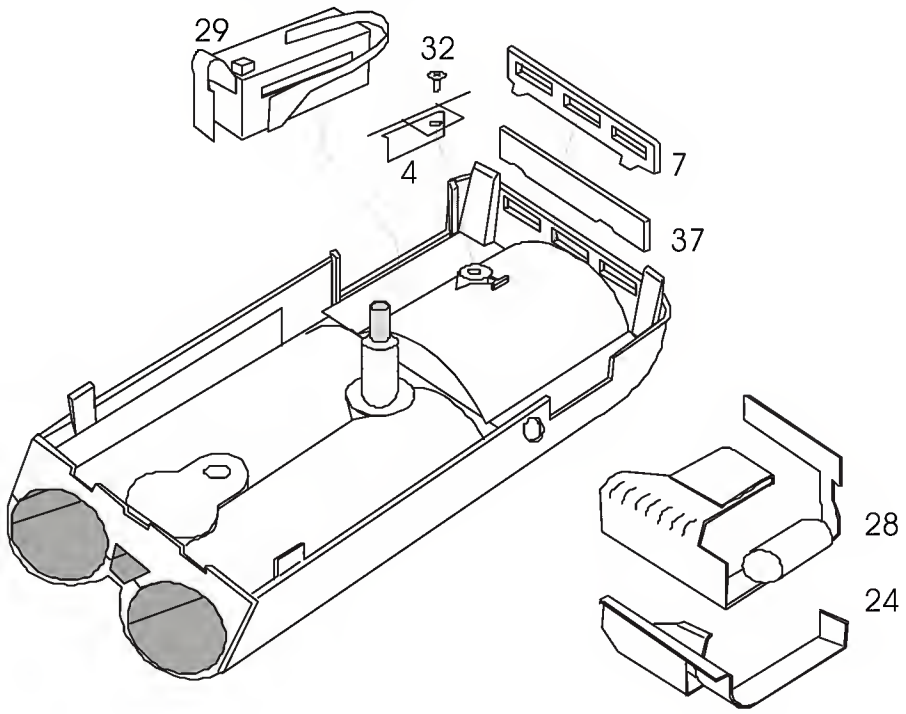

Figure 12.11 Printer and Flex Circuit installation

1. Remove the printer button stiffener (37).

2. Disconnect the two flex-circuit headers of the printer (29) from the connectors on the printer flex circuit (28) by slowly pulling outward from side to side at alternating ends of the connectors.

3. Remove the printer button strip (7) from the printer flex-circuit.

4. Remove the printer flex-circuit insulator (24).

5. Remove printer hold-down bracket (4) from the back cover by removing the Phillips screw (32).

6. Press the printer hold-down bracket into the back cover and remove the printer.

WARNING: Disassembly of the instrument exposes hazardous voltages. To avoid injury or instrument damage, disassembly or maintenance must be attempted only by qualified service personnel.

Troubleshooting Guide

This section discusses potential symptoms, possible causes, and actions for their resolution. Should this trouble-shooting guide fail to address the symptoms evident in a particular N-20P, please contact Nellcor Technical Services Department or a local Nellcor representative for assistance.

If the N-20P does not perform as expected:

- Check for proper sensor placement
- Depending on concentration, indocyanine green, methylene blue, and other intravascular dyes may affect the accuracy of a measurement.
- These instruments are calibrated to read oxygen saturation of functional arterial hemoglobin (saturation of hemoglobin functionally capable of transporting oxygen in the arteries), significant levels of dysfunctional hemoglobins such as carboxyhemoglobin or methemoglobin may affect the accuracy of a measurement.

If the electronics and/or display functions require testing, refer to "Test and Calibration" in this manual.

SYMPTOM 1: No response to measure button.

CAUSE 1: Battery access door may not be properly latched.
ACTION 1: Check access door and ensure it is properly latched.

CAUSE 2: Batteries may be discharged.
ACTION 2: Exchange them for a new set.

CAUSE 3: Batteries may be incorrectly installed.
ACTION 3: Ensure that batteries are oriented according to the polarity indicator.

CAUSE 4: Batteries may not be making proper electrical contact.
ACTION 4: Inspect contacts for deformity; clean contacts to remove oxidation.

CAUSE 5: Fuse F1 on the auxiliary PCB may be open.
ACTION 5: See "Fuse Replacement"

CAUSE 6: Dust may have accumulated under measure button causing loss of electrical contact.
ACTION 6: Clean contact points under measure button (see "Disassembly Procedure").

SYMPTOM 2: Pulse Search indicator appears for more than 5-10 seconds.

CAUSE 1: Sensor may be improperly positioned.
ACTION 1: Ensure the sensor is correctly applied (see sensor directions for use).

CAUSE 2: Incorrect sensor may be in use.
ACTION 2: See sensor directions for use to ensure that the patient's weight and sensor application are correct. Test the sensor on another person to verify proper operation.

CAUSE 3: Perfusion may be too low.
ACTION 3: Check patient status. Test the instrument on someone else, or try another type of sensor. The N-20P will not make a measurement if perfusion is inadequate.

CAUSE 4: Foreign material on the sensor LEDs or photodetector may be affecting performance.
ACTION 4: Clean the test area and ensure that nothing blocks the sensor site.

CAUSE 5: Patient motion may be interfering with the instrument's ability to find a pulse pattern.
CAUSE 6: Environmental motion may be interfering with the instrument's ability to track a pulse.
CAUSE 7: The sensor may be too tight, there may be excessive illumination (e.g., a surgical or bilirubin lamp or direct sunlight), or the sensor may be placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
ACTION 5-7: If possible, ask the patient to remain still. Verify that the sensor is securely applied and replace it if necessary, move it to a new site, or use a sensor that tolerates patient movement, such as an appropriate adhesive sensor.

CAUSE 8: The DB-9 sensor connector on the N-20P may be broken.
ACTION 8: Replace the DB-9 connector.

SYMPTOM 3: Pulse Search indicator appears after successful measurements have been made.

CAUSE 1: Patient perfusion may be too low.
ACTION 1: Check patient status. Test the instrument on someone else, or try another type of sensor. The N-20P will not make a measurement if perfusion is inadequate.

CAUSE 2: Patient motion may be interfering with the instrument's ability to find a pulse pattern.
CAUSE 3: Environmental motion may be interfering with the instrument's ability to track a pulse. The sensor may be too tight, there may be excessive illumination (e.g., a surgical or bilirubin lamp or direct sunlight), or the sensor may be placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
ACTION 2,3: If possible, ask the patient to remain still. Verify that the sensor is securely applied and replace it if necessary, move it to a new site, or use a sensor that tolerates patient movement, such as an appropriate adhesive sensor.

SYMPTOM 4: Dashes (- - -) appear in the display.

CAUSE 1: The sensor is not connected to the instrument.
ACTION 1: Check all sensor connections; try substituting another sensor. Check all extensions cables. If an extension cable is in use, remove it and plug the sensor directly into the instrument.

SYMPTOM 5: Pr Err is displayed during the POST.

CAUSE 1: The printer is not operational, but the N-20P continues to obtain patient measurements.
ACTION 1: Check to see if the paper is jammed. Examine the print head and ensure that it has returned to the home position.

SYMPTOM 6: Err followed by a number appears on the display.

CAUSE 1: See "Error Codes" in this manual.
ACTION 1: Record the number that is displayed.

SYMPTOM 7: Time or date is incorrect.

CAUSE 1: The real-time clock battery may be exhausted.
ACTION 1: Replace the RTC battery. Reset the time and date.

SYMPTOM 8: Printer fails to operate.

CAUSE 1: Fuse F2 on the auxiliary PCB may be open.
ACTION 1: See "Replacing Fuses" in this manual.

SYMPTOM 9: Printer paper advances but instrument does not print.

CAUSE 1: The thermal paper may be improperly loaded; characters can be printed on only one side of the thermal paper roll.
ACTION 1: Ensure that the thermal paper is properly loaded; if needed, remove the roll of printer paper and reload the printer paper.

SYMPTOM 10: Paper mechanism jams.

NOTE: If a printer paper jam is detected during POST, Pr Err may appear on the display.

ACTION 1: Switch off the N-20P. Then check to see if the print head is at the home position, if so, attempt to pull the paper out by pulling gently – do not force it.

If the print head is not a the home position, and the paper cannot be easily pulled out from the printer, then the printer may need to be disassembled to remove the paper jam (see "Disassembly Procedure" and "Loading/ Clearing Printer Paper").

12.5 Parts List

N-20P Spare Parts. To order replacement parts, contact Nellcor Puritan Bennett's Technical Service Department at 1-800-NELLCOR and order by part number.

Item	Designator	Description	P/N
1.	SW1	Battery switch (auxiliary PCB)	630106
2.	BTi	Battery holder (auxiliary PCB)	901582
3.	BTi	Battery, lithium (auxiliary PCB)	640112
4.		Bracket, printer, hold-down	203133
5.		Button, battery-check	023301
6.	S2	Button, measure	022948
7.		Buttons, printer, strip	022947
8.	L1, L2	Coil, 120 µH SMT (auxiliary PCB)	691238
9.		Connector shield, DB-9	463103
10.		Connector, DB-9	463103
11.	JP17, JP18	Connector, pin header 1Ox2, low profile (auxiliary PCB)	491244
12.	JP5	Connector, ZIF, flex, 7-pin (auxiliary PCB)	491242
13.	JP9	Connector, ZIF, flex, 22-pin (auxiliary PCB)	491250
14.	JP2,3	Connector, ZIF, flex, 32-pin (auxiliary PCB)	491243
15.		Cover, battery, rear (non-printer model)	022929
16.		Cover, front, with gasket assembly	022921
17.	D8	Diode, photo, 8440 (main PCB)	591017
18.		Display, Taliq, analog shield assembly	024466
19.		Door, battery	022924
20.		Door, paper	022938
21.		Door, printer	026338
22.	F2	Fuse, micro, 1 amp (auxiliary PCB)	691236
23.	F1	Fuse, micro, 1.5 amp (auxiliary PCB)	691239
24.		Insulator, printer	026139
25.		Nut, keps, SS, 4-40	851101
26.		PCB, auxiliary	024472
27.		PCB-B, main	024468
28.		Printer flex circuit	024464
29.		Printer	024462
30.		Screw cap	023451
31.		Screw, captive	891324
32.		Screw, Philips, 4-40 X 1/4	801025

Item	Designator	Description	P/N
33.		Screw, plastite	871031
34.		Sensor lock	022943
35.		Sensor shroud	022944
36.		Spacer	023452
37.		Stiffener, printer button	023131
38.		Tap, foam (.88" x .38")	023300
39.	BZ1	Transducer, audio, piezo ceramic	691230

12.7 Specifications for N-20P

Components

- N-20P pulse oximeter
- Four alkaline "C" size batteries
- *DURASENSOR*® DS-100A oxygen transducer
- 2 *OXISENSOR* D-25L oxygen transducers
- EC-4 sensor extension cable
- Protective rubber boot (includes shoulder strap and hand strap)
- N-20 operator's manual
- Integrated printer and one case (12 rolls) of thermal paper (N-20P only)

Readout

Display showing SpO_2 (arterial hemoglobin oxygen saturation), pulse rate, and pulse amplitude; also included are a Pulse Search and Low Battery indicator, and an electroluminescent backlight.

Controls

N-20P:

- Measure button switches instrument on, initiates measurement cycle, and switches instrument off.
- Battery check button is used to check battery condition and switches beeper on and off.
- ON button switches the printer on and off.
- D/D sets display date and time.
- ADV advances and increments time and date.

Spot Check Operating Mode

Spot check mode is started by depressing the instrument measure button once. Spot check mode computes SpO_2 averaged over five valid pulses and displays SpO_2 and pulse rate at the end of the measurement interval. If the printer is activated, the printout shows the displayed SpO_2 and pulse rate.

Extended Operating Mode

Extended mode is started by holding down the instrument measure button for approximately 3 seconds, plus any time required to complete the power-on self test. The N-20P displays updated SpO_2 and pulse rate with every pulse (after five valid pulses have been detected). The N-20P remains active until 3 minutes after the sensor is removed, until the instrument is turned off, or until 30 minutes have elapsed since the last detected pulse.

The N-20P printout shows SpO_2 and pulse rate at 30-second intervals. The N-20P will indicate any 2% decrease in SpO_2. This event is signaled by two brief, low-pitched tones and an asterisk (*) on the N-20P printout. At the end of the measurement period, a header and statistical summary values (minimum, maximum, and mean of both pulse rate and oxygen saturation) are printed.

Printer Output

When activated by the printer ON button, the N-20Ps output shows: date, time, SpO_2, and pulse rate (in spot check mode), with space provided for writing in patient identification. The thermal paper printout measures roughly 40 mm (=1.6 in.) by 100 mm (=4.0 in.) in size.

If the N-20P is in spot check mode and the printer is turned on any time during a measurement or after a measurement is taken and before the N-20P powers down, the printer will catch up and print a complete record of the measurements recorded up to the current moment.

N-20P Performance

RANGE

Saturation:	0-100%
Pulse Rate:	20-250 beats per minute (bpm) ± 1 standard deviation[2]

SpO2 Accuracy 1

Adults:	70-95%	± 2 digits[2]
	50-69%	± 3 digits[2]
	0-49%	unspecified
Neonates:	70-95%	± 3 digits[2]
Pulse Rate:	20-250 bpm	± 3 digits[2]

Response

In spot check mode, the measurement cycle (from button press to display of data) is five valid pulses, depending on patient pulse rate and perfusion.

In extended mode, the instrument measures for a period of up to 30 minutes and continuously displays updated SpO_2 and pulse rate.

1. Accuracy is based upon testing an Oxisensor D-25 oxygen transducer. 68% of the measurements across the population will be within ±1SD (standard deviation). Testing to verify these specifications is performed against Nellcor N-20P pulse oximeters with D-25 sensors that have been previously validated for accuracy against an Instrumentation Laboratories Co-Oximeter. The accuracy specification for neonates is based on measurements taken with Oxisensor N-25 oxygen transducers. For specification of accuracies with other NELLCOR sensors, see the sensor package insert.

2. This variation equals 1SD.

Sensor Types

SENSOR	Model	Patient Size
OXISENSOR oxygen transducers:	N-25	<3 or >40 kg
	I-20	1-20 kg
	D-20	10-50 kg
	D-25, D-25L	>30 kg
	R-15	>50 kg
OXIBAND® oxygen transducers:	OXI-A/N	<3 or >50 kg
	OXI-P/I	<3 - 40 kg
NELLCOR reflecting oxygen transducer:	RS-10	>40 kg
DURASENSOR® oxygen transducer:	DS-100A	>40 kg
DURAFORM™ oxygen transducer:	DF-A	>40 kg

NOTE: DURAFORM oxygen transducers are not available for sale in Europe.

Electrical Specifications

BATTERY

Type:	Four 1.5 V alkaline "C" batteries
Battery Capacity:	N-20P ≈ 32 hours, typical

Note: Not all brands of off-the-shelf batteries provide the same battery life.

INSTRUMENT

Power Requirements:	4-6 VDC, supplied by battery only
Leakage Current:	Negligible; the N-20P has no power or ground connections
Patient Isolation:	No electrical connection to patient (inherently insulated)